Outlook

Naval Medical Research and Development Command

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On The Cutting Edge of Medical Research Today *April 1992*

NAVY UNIT COMMENDATION AWARDED TO NMRDC, NMRI, NAMRU-3, NHRC, NAMRL

The Secretary of the Navy awarded the Navy Unit Commendation to the Naval Medical Research and Development Command (NMRDC), the Naval Medical Research Institute (NMRI), the U.S. Naval Medical Research Unit No. 3 (NAMRU-3), the Naval Health Research Center (NHRC), the Naval Aerospace Medical Research Laboratory (NAMRL) and the Navy Environmental and Preventive Medicine Unit No. 7. In a letter forwarded 24 January 1992 the Secretary of the Navy approved the award for military and civilian personnel at the cited activities in recognition of their outstanding service during Operations Desert Shield/Desert Storm.

During the period 2 August 1990 to 28 February 1991, NMRDC and its subordinate laboratories, assisted by the Navy Environmental and Preventive Medicine Unit No. 7, contributed to the success of Operations Desert Shield/Desert Storm. NMRDC quickly initiated efforts to establish and operate a state-of-the-art infectious disease diagnostic laboratory to complement the medical capabilities within theater. The laboratory allowed researchers to track diseases which were disabling front-line U.S. and allied troops. The laboratory was staffed by infectious disease specialists from NMRDC, NMRI and NAMRU-3 and an environmental health officer from NHRC. The laboratory, with effective support from NMRI and NAMRU-3, provided Navy medicine with the ability to rapidly diagnose and treat the rare diseases of the area. Lost time due to disease was greatly reduced. The laboratory also provided the only on-site capability to identify specific biologic threats.

In addition to assisting with the threats of infectious disease, the medical research community effectively provided support for improving the performance of personnel under the harsh conditions of the area. NHRC accelerated laboratory studies associated with the use of microclimate cooling vests for extended performance in hot environments in order to provide working guidance for the use of the vests. NHRC, in cooperation with NAMRL, performed research on hydration and short-term hyperhydration techniques to enhance and balance body water storage and minimize water loss under the harsh environmental conditions. NAMRL deployed research teams to evaluate performance of aircrew personnel under combat stress and provided suggested modifications in scheduling.

INSIDE THIS ISSUE:

OPPORTUNITIES FOR INCREASED TECHBASE FUNDING IN FY93 AND THE OUT YEARS

Investigators and laboratories exploring additional funding opportunities should know that there are a number of existing avenues to increase or replace R&D funds.

The primary source of basic research (6.1) funding within the Navy is the Office of Naval Research (ONR). ONR provides NMRDC with an allocation of funds for core projects, for Independent Research (IR) and for Accelerated Research Initiatives (ARI). IRs and ARIs are awarded by NMRDC following competitive peer review.

Navy funding for exploratory development (6.2) projects is provided to NMRDC by the Office of Naval Technology (ONT). ONT funds are used mainly to support on-going applied research thrusts but a limited amount of these funds is invested each year into NMRDC's internal "Independent Exploratory Development" program.

The Office of Advanced Technology (OAT) provides out year funding (6.3A) for Advanced Technology Demonstration (ATD) projects. Investigators involved in research projects that address problems shared by the private sector may also look into Cooperative Research and Development Agreements (CRDA).

INDEPENDENT RESEARCH
(P.E. 61101D)

The Independent Research (IR) Program offers investigators the opportunity to compete for basic research (6.1) funding in an NIH grant-type system (see NAVMEDRSCHDEVCOMINST 3902.1 of 18 May 1990). Investigators can submit innovative, basic research proposals to NMRDC's Director of Research and Development. Proposals are prioritized for funding primarily on the basis of scientific merit as judged by external peer review.

Principal investigators of IR projects have full authority for the resources allocated to the project and also have singular accountability for the successful execution of the research. IR projects can span a period of 1 - 3 years and typically are funded in the range of $60 - 120K. For FY93, NMRDC's IR program budget is planned at $1,245K which will support approximately 14 studies. Historically, the IR program has proven to be a good *spring board* for outstanding IRs to compete successfully as 6.1 Accelerated Research Initiatives (ARI).

For FY93, IR proposals were due on 16 March 1992 and evaluations from external reviewers are due on 15 April 1992. Investigators will be notified of the selection of IR proposals by 1 May 1992.

Examples of IRs currently funded:

- The Role of Lymphokines in the Generation and Maintenance of Enteric Immune Responses in Mice (FY90) NMRI Dr. Rollwagen
- Studies on Purified Cord Blood Hematopoietic Stem Cells (CD34+ Cells) (FY91) NMRI Dr. Kessler
- Plasma Volume, Vasopressin, and the Genetics of Motion Sickness (FY92) NHRC Dr. Lockette
- The Use of LEET and Bright Light Separately and Together for Shifting the Work/Rest Cycle (FY92) NHRC Dr. Kelly
- Determination of the Mechanisms of Endothelial Injury During Bone Marrow Transplantation (FY92) NMRI CAPT Cahill

DEFENSE RESEARCH SCIENCES
(P.E. 61153N and 61102D)

In the Defense Research Sciences Program (NMRDC's main 6.1 program), the primary opportunity for securing new start funding for the out years (two years out) is through an Accelerated Research Initiative (ARI). An ARI is defined by ONR as, " a concentration of resources for a finite time in a promising area of science for the purpose of accelerating research progress and for providing the means for capitalizing on scientific opportunities or responding to a critical Navy requirement in a particular area." ARIs are competitively awarded on the basis of recommendations of external peer selection committees composed of scientific and Navy requirements experts. ARIs typically are funded at $400K - $600K per year for 3 - 5 years. The next ARI opportunity will be the FY93 cycle, which will result in the selection of a study to be funded beginning in FY95. For the FY93 ARI competition, preproposals (1-2 page narratives describing the research effort) are due on 1 July 1992. Proposers of studies selected to advance into the ARI competition will be notified by 1 September 1992, and full research proposals are due on 15 December 1992.

ARIs currently funded or selected for funding include:

- Vestibular Transduction (FY88) NAMRL Dr. Guedry
- Cell Biology of Trauma (FY89) NMRI LCDR Robinson
- Non-Freezing Cold Injury (FY90) NMRI Dr. Thomas, NAMRL Dr. Lotz
- Hydrogen Diving (FY91) NMRI Dr. Harabin
- Cold-Induced Amnesia (FY92) NMRI LT Ahlers
- Spatial Orientation (FY93) NAMRL Dr. Guedry
- Evoked Otocoustic Emissions and Inner Ear Damage from Noise Exposure (FY94) NSMRL Dr. Marshall

In addition to ARIs, the Defense Research Sciences Program offers another out year funding opportunity called Program Enhancements (PE). ONR defines PE as, " limited-dollar complements to existing 6.1 basic research studies" and requires that the research has already had some level of prior support by NMRDC. Typical funding for PE is in the range of $150K - 200K per year for 3 - 5 five years. Investigators should follow the preproposal/ proposal submission guidelines listed for ARIs, but should indicate on the documentation that the proposal is submitted as a PE candidate.

PE currently funded include:

- Septic Shock Proteins (FY91) NMRI Dr. Williams
- Hepatic Receptors in Sepsis (FY92) NMRI Dr. Williams
- Enhanced Angiogenesis (FY92) NMRI Dr. Nielsen

INDEPENDENT EXPLORATORY DEVELOPMENT (P.E. 62233N)

The Independent Exploratory Development (IED) Program is an Office of Naval Technology (ONT) sponsored program which has the same goals as the IR program, except that IED projects are more applied (6.2) than are IR projects. ONT has not included NMRDC in the official IED program; however, in order to create new 6.2 opportunities for in-house investigators, NMRDC has developed its own IED program. As in IR, IED projects are selected following competitive peer review and are restricted to the same funding ranges and durations. Investigators interested in submitting IED proposals should follow the IR guidance on submission deadlines and peer review requirements.

IEDs currently funded include:

- An Evaluation of Alternative Symbolic Designs for Maritime Tactical Displays (FY91) NSMRL LT Van Orden
- Nanoparticle Delivery of an Endotoxin Binding Agent and Antibacterial Quinoline in Sepsis (FY92) NMRI Dr. Nevola

ADVANCED TECHNOLOGY DEMONSTRATION (P.E. 63792N)

Advanced Technology Demonstration (ATD) projects are selected each year by the Office of Advanced Technology (OAT) for funding in the out year programs (two years out). ATDs are 1 - 3 year advanced development studies, funded upwards of $1M per year. These studies focus on promising, often high risk, emerging technological opportunities and are designed as risk-reducing "proof of principle" studies that demonstrate the potential for a new operational capability or a significant improvement in cost-effectiveness. A clear transition plan and an explicit sponsor for post-ATD work are essential. OAT's call for proposals usually occurs in May. ATD concepts should be thoroughly coordinated with the appropriate Research Area Manager beginning in early April. NMRDC is required to prioritize all ATD candidates for submission in mid-September. Selected ATDs are presented to the sponsor's selection committee in late November.

ATDs currently funded or selected for funding include:

- Synthetic Red Blood Cells (FY90) NMRDC
- Combat Wound Management (FY90) NMRDC
- Freeze Dried Red Blood Cells and Platelets (FY93) NMRDC
- Auditory Interface for Transients Processing (FY94) NSMRL

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CRDA)

A CRDA is an agreement under the technology transfer statutes that permits the unique capabilities or inventions of a Government laboratory to be supported by a collaborator in the private sector. Instructions on entering into and processing CRDAs are available from NMRDC intellectual property counsel (Code 00L)

Examples of current CRDAs:

- NMRDC (NMRI)/Pharmingen, Develop and market cell line products for use in antibody testing
- NMRDC (NAMRL)/Univ. of IL, Joint research on effects of fatigue on skilled performance
- NMRDC (NDRI Det. Bethesda)/COLLA-TEC, Test COLLA-TEC's resorbable membrane in surgical repair of mandibular defects

RDT&E Program Element Definitions

6.1	**Basic Research** is directed towards increasing essential fundamental scientific knowledge of broad benefit to Naval operational needs and technology applications.
6.2	**Exploratory Development** focuses on the feasibility of basic research concepts and discoveries to solve specific future Naval needs.
6.3A	**Advanced Technology Development** addresses specific advanced concept, technology, and development options directed at implementation feasibility and risk reduction demonstrations for innovative solutions to Naval needs prior to full scale development.
6.3B	**Advanced Development** further validates a development option based on hardware evaluation to provide improved definition of system characteristics, risk expectations, and final outcome.
6.4	**Engineering Development** supports full scale development phases including hardware characteristics, fabrication details, training, maintenance, and operational manuals, and full test and evaluation prior to production phases.

NAVY HELD THIRD ANNUAL INFORMATION EXCHANGE CONFERENCE IN EARLY APRIL

by Chirstine Eiseman, Associate Director for Research Management

On 8-10 April 1992, scientists from the Navy research and development community and a number of civilian laboratories convened at the Naval Surface Warfare Center (NSWC), White Oak Detachment (Silver Spring, MD) for the Third Navy R&D Information Exchange Conference.

The purpose of this conference was to facilitate the exchange of R&D information among Navy engineers and scientists, to stimulate cooperative thinking and collaborative projects, and to familiarize Navy technologists with the equipment and personnel resources that exist in sister laboratories. The conference organizers recognized the fact that the dynamic interaction among Navy scientists, the active flow of technological information across laboratories and the coordination of resources must underpin the R&D community's support of the high tech operational Navy of the future. Conference supporters believe that such interaction can best be achieved not at the managerial level, but by the Navy bench scientists who understand the technologies that can be blended to solve the Navy's most difficult operational problems.

The Naval Submarine Medical Research Laboratory (NSMRL), Groton, CT; the Naval Health Research Center (NHRC), San Diego, CA; and the Naval Medical Research Institute (NMRI), Bethesda, MD joined in this conference with the Navy's new "megacenter" laboratories: Naval Surface Warfare Center; Naval Command, Control and Ocean Surveillance Center; Naval Air Warfare Center; Naval Undersea Warfare Center; as well as the Johns Hopkins Applied Physics Laboratory.

Dr. Thomas Clare, Executive Director of NSWC's Dahlgren Division, kicked off the conference with welcoming remarks that lead into three days of oral and poster presentations and facilities tours. Tours included the NSWC wind tunnel, the positive ion accelerator, and equipment for studies in magnetic ships silencing and hydroballistics.

The scientific sessions were divided into Non-linear Dynamics, Materials, Information Sciences, Medical and Biological Sciences, and Systems Technology. The NMRDC laboratories presented eight of the 129 talks and five of the 28 posters scheduled. Not surprisingly, most of the NMRDC laboratory studies were placed in the Medical and Biological Sciences session, which included talks on advances in biotechnology, physiology, and human factors research. One talk by Dr. Tom Santoro (NSMRL), however, was scheduled to be presented in the Systems Technology Session along with other hardware-oriented studies.

Bravo Zulu to all the NMRDC scientists who submitted abstracts and posters to this Navy conference, including:

- Effect of Bearing Indicator Design on a Target Detection and Bearing Awareness Task
  T. Santoro (NSMRL)
- A Navigational Performance Comparison of Simulated Visual Range Indicators
  K. Laxar (NSMRL)
- Contributions of Envelope Information to the Aural Classification of Brief Sounds
  T. Hanna (NSMRL)
- Effect of High Ambient Heat and Cooling on Heart Rate Drift and Work Endurance
  R. Pozos (NHRC)
- The Effects of Microclimate Cooling on Total Body Sweat Rate and Vasoactive Intestinal Peptide
  J. Heaney (NHRC)
- Detection of West Nile Virus by the Polymerase Chain Reaction and Analysis of Strain Variation
  K. R. Porter (NMRI)
- Molecular Advances in the Detection and Identification of Rickettsiae
  G. A. Dasch (NMRI)
- Administration of Recombinant Human Factors Ameliorates the Severity of Neutropenia After Exposure to Mustard Agents
  R. L. Monroy (NMRI)
- Declining Trends in Human Immunodeficiency Virus (HIV) Seropositivity in Active-Duty U.S. Navy Enlisted Personnel
  F.C. Garland (NHRC/poster)
- Incidence of First Hospitalizations for Diabetes Mellitus in the U.S. Navy Active Duty Enlisted Personnel
  E.D. Gorham (NHRC/poster)
- Effects of L-Tyrosine Administration on Cold Induced Memory Deficits
  J. Schrot (NMRI/poster)
- Physiological Responses Following Fluid Hyperhydration During High Heat Exposure
  B.L. Bennett (NHRC/poster)
- Physiological Parameters Relating Cardiovascular Drift in High Heat/Low Humidity Conditions
  D. Trone (NHRC/poster)

OUT YEAR FUNDING FOR MEDICAL AND NON-MEDICAL PROGRAMS LOOKS SOLID

by CAPT E. T. Flynn, Commanding Officer

In the last issue I spoke of the Under Secretary of Defense's Oct 1 Memorandum which proposed consolidation of medical research and development under the Assistant Secretary of Defense for Health Affairs. After much debate, it appears clear that DoD intends to proceed with this plan beginning in FY93.

We have attempted to position ourselves as best we can in this new environment. To start, we split our programs into "medical" and "non-medical". Medical programs are defined as those in which the medical department or a patient is the end-user. The medical programs consist of infectious disease, combat casualty care, chemical and biologic defense research, and studies and analysis.

Non-medical programs are defined as those in which the line Navy is the end-user. The non-medical programs consist of diving, submarine, surface, and aviation medicine; human performance; and occupational and environmental health.

Program Budget Decision 742 transferred all money associated with the medical program from the Navy to the Assistant Secretary of Defense for Health Affairs. We have been very active on the DoD POM process to ensure that these programs will be fully funded in the out years. Since the Armed Services Biomedical Research Evaluation and Management Committee (ASBREM) will be advising the Assistant Secretary of Defense for Health Affairs on how to divide medical research money between the Services, we have been working hard to put a structure in place that will ensure open and fair competition. Congress has helped by appointing the Director, Defense Research and Engineering and the Assistant Secretary of Defense for Health Affairs to serve as the co-chairmen of ASBREM.

Money associated with the non-medical programs will stay within the Navy and these program will operate as they previously have.

Excellent briefings on various aspects of the non-medical program were given to VADM Reynolds (OP-091) and the Science and Technology Working Group by CDR R.C. Carter, CDR P.D. Kent, and CDR L.J. Yaffe (NMRDC) and by CAPT D.W. Call (NBDL). All of these briefings have opened up the possibility of increased funding for the out years.

There are serious on-going concerns with out year reductions in the military and civilian workforce that remain to be resolved. We are extremely hopeful of preserving our full complement of military and civilian personnel in the deliberations to come.

In summary, out year funding in both the medical and non-medical programs looks solid. If the medical research program reverts to the Services during the course of the Congressional or DoD POM-94 debate, all the infrastructure to return these programs to the Navy has been preserved. We feel confident we are in the best position we can be in.

DATES TO REMEMBER

March 1992

- 16: FY93 IR proposals due NMRDC

April 1992

- 5: Daylight Savings, set ahead 1 hour
- 8-10: Navy Information Exchange Conference
- 15: External IR reviews due NMRDC

May 1992

- 1: Investigators notified of IR proposal selection
- 1: FY93 Guidance issued (including IR/IED and new starts)
- 8: Second Interim Reports due at NMRDC
- 20: Call for FY95 Advanced Technology Demonstration (ATD) proposals

June 1992

- 1: DD1498s/addenda and budgets due at NMRDC

July 1992

- 1: ARI Preproposals due NMRDC

September 1992

- 1: Investigators notified of proposals selected to advance into the ARI competition
- 1: ATDs due to NMRDC

Personnel Notes:

CDR RAY OLAFSON , MC, USN, ASSISTS WITH JAPANESE ENCEPHALITIS VACCINE STUDY IN OKINAWA

CDR Ray Olafson, MC, USN (NAMRU-2) joins scientists from the Navy Environmental Health Center and the Navy Environmental and Preventive Medicine Unit No. 6 to assist the U.S. Naval Hospital, Okinawa in a study of the prevalence of Japanese encephalitis and the safety of a vaccine developed and produced in Japan.

Military personnel, their dependents and civilians living and working in Japan, China, the Philippines, Southeast Asia, and parts of Indonesia are at risk of getting the disease.

CDR Olafson has an MD and PhD with 10 years of research experience before joining the Navy. He was Head of the Research Department at the Naval Aerospace Medical Research Laboratory prior to his assignment to NAMRU-2. He is familiar with the administrative requirements relative to a large research project. CDR Olafson has a strong background in clinical and operational medicine and his knowledge of the Japanese language and customs is an added benefit to his work on this project.

This is the largest controlled study of a vaccine undertaken by the Navy. The data obtained will contribute to the approval process by the FDA and provide a scientific basis for policy decisions made by the Navy, Marine Corps, Army and Air Force on the use of the vaccine for DoD personnel and dependents assigned to bases in the Far East.

NBDL's OUTSTANDING PRT RESULTS

The results of NBDL's PRT: 77 percent of the personnel assigned scored in the excellent or outstanding categories.

Naval Biodynamics Laboratory's (NBDL) Physical Readiness Test (PRT) results stand above the crowd. These individuals serve as role models for the rest of the Navy as examples of physical fitness and healthy lifestyles!

The PRT is a semi-annual human performance test and all Navy personnel are required to participated unless they are medically restricted or over the age of 50. The test is performed each Spring and Fall and involves four basic components: sit-reach, curl-ups, push-ups and the 1.5 mile run/walk or an alternative 500 yard swim. OPNAVINST 6110.1d is the governing instruction for the PRT program.

NAMRL REMEMBERS MISS BAKER

by Kathleen S. Mayer, Technical Editor, NAMRL

In a formal ceremony on February 14, CAPT A. Mateczun, Commanding Officer of NAMRL, presented artifacts of the famous squirrel monkey, Miss Baker, to the director of the National Museum of Naval Aviation, CAPT Robert Rasmusen, USN, (Ret.). Among those attending were Dr. Donald E. Stulken, space physiologist on the recovery team, and Dr. Jorma I. Niven, assistant director of research.

Weighting less than 1 pound and enclosed in a biocapsule the size of a thermos,Miss Baker, was launched on May 28, 1959 at 0235:02 EST in the nose cone of a Jupiter missle. The Army chose her flight companion, a 7-pound male rehesus monkey named Able, who was housed in a separate biocapsule. Wearing special space suits and helmets designed to protect them from radiation and temperature changes, Miss Baker and Able were propelled 360 miles into space at a rate of 10,000 miles per hour. One hour and 33 minutes after launch, the nose cone was hoisted up--250 miles from San Juan, Puerto Rico.

The entire flight lasted about 15 minutes, but it marked the beginning of space exploration as we know it today. News of their successful voyage reached all over the world. Able died 4 days after reentry but Miss Baker returned to Pensacola a heroine. The American Society for the Prevention of Cruelty to Animals awarded Miss Baker a gold medal and a certificate of distinguished service. Miss Baker retired to a special housing unit in Pensacola where visitors could pay her homage through a one-way window. On June 30, 1971, she was transferred to the US Space and Rocket Center, Huntsville, Alabama, where she remained until her death on November 20, 1984.

The artifacts included the complete biocapsule, the original telemetry reports, EKG leads, engineerring dimensional photographs, and helmet.

Contributions to Personnel Notes should be sent to NMRDC, CODE 09D, NNMC, Bethesda, MD 20889-5044 or by E-mail rdc09d@nmrdc1. nmrdc.nnmc.navy.mil

Personnel Notes:

DR. LYNNE MARSHALL (NSMRL) WINS COMPETITION FOR FY94 ARI

On 5 March 1992, a panel of external scientists met at NMRDC to evaluate and discuss four research proposals competing for FY94 funding as an Accelerated Research Initiative (ARI). The committee consisted of Dr. C. R. Valeri (Naval Blood Research Laboratory), Dr. Adrian Barbul (Sinai Hospital), Dr. Amrit Judd (SRI International), Dr. Howard Hawkins (Office of Naval Research), Dr. James Howard (Catholic University), and Dr. Glenis Long (Purdue University).

Although panel members had already studied the written proposals, the meeting gave them an opportunity to listen to oral presentations and discuss issues with the proposals' principal investigators. The panel's deliberations and scoring led to their enthusiastic selection of the study proposed by Dr. Lynne Marshall (NSMRL), "Evoked Otoacoustic Emissions (EOAEs) and Inner Ear Damage from Noise Exposure."

EOAEs are sounds that are emitted by the ear in response to a stimulus. According to Dr. Marshall, EOAEs "are generated by the outer hair cells in the inner ear. These sounds travel through the middle ear to the ear canal, where they can be measured with a sensitive microphone and appropriate signal-processing techniques. Because the outer hair cells are adversely affected by intense noise exposure, otoacoustic emissions may provide a sensitive and objective way to monitor the effects of noise exposure."

Dr. Marshall's proposal intrigued the committee as a novel approach to a health issue which is critically important to Navy medicine. Hearing injury due to noise exposure and the associated manpower and compensation costs are continual problems for the Navy, both in time of peace as well as in time of war.

Current tests which assess the effects of noise on hearing cannot detect early stages of hearing loss and give no information about an individual's susceptibility to noise or his fitness for duty relative to specific operational tasks.

These deficiencies cause the Navy to suffer decrements in hearing-dependent job performance, to lose trained personnel due to hearing injury, and incur large treatment and workman's compensation costs for veterans ($2.2B over the last 20 years) and civilian employees ($6M to the Navy in 1989) who suffered hearing injury while performing Navy jobs. Dr. Marshall's research is particularly appropriate for funding by the Navy, which operates in numerous unique, high-noise work environments. Additionally, such research on adult hearing loss and EOAEs is not being conducted to a large extent by the civilian research community.

Dr. Marshall will receive approximately $350K for her study in FY94 and similar funding each year through FY98. Congratulations to Dr. Marshall for her outstanding proposal and presentation and thanks to the other investigators for their participation in this research competition: Dr. Florence Rollwagen (NMRI), CDR Lyn Yaffe (NMRDC), and Dr. Joseph DiVita (NSMRL).

Note:

The next ARI awards will be made in FY93 for funding beginning in FY95. In response to requests from a number of investigators, the ARI schedule will be accelerated as follows:

ARI preproposals (1-3 pgs) will be due on 1 July 1992.

NMRDC's selection of preproposals to be developed into full ARI proposals will be announced on 1 September 1992.

Full ARI proposals will be due on 15 December 1992.

The ARI competition will be held in early March 1993.

CAPT RALLS, DC, USN NEW DENTAL RAM

CAPT Stephen A. Ralls, DC, USN, has been assigned as NMRDC's Research Area Manager (RAM) for Dental Research. CAPT Ralls is currently assigned to the Bureau of Medicine and Surgery, Washington, DC as the Dental Corps Plans/Career Development Officer. His additional duties in this assignment will include the development of research sponsorship, research requirements, guidance to performers, and briefings. In addition, he will collaborate with the NMRDC subordinate labs to develop a dental research program which is scientifically excellent, responsive to Navy needs and requirements, executable, viable in the evolving political and economic environments, and coordinated across the various funding sources and performers.

EMERGENCY EYEWASH STATIONS

by Kip Johnson, NMRDC Staff Assistant for Occupational Safety

One of the most devastating injuries a laboratory worker can suffer is the loss of eyesight. Although safety eyewear such as side shields, goggles or face shields are required when working with chemicals, should these measures fail and corrosive chemicals enter the eye, an effective emergency eyewash station is essential for immediate first aid treatment.

Many questions have been asked by lab personnel concerning location guidelines, types and performance qualifications of emergency eyewash stations. The American National Standards Institute (ANSI) standard Z358·1 of 1990 outlines the specifications for emergency eyewash and shower stations. Figure 1 notes some of the mounting requirements of a combination unit.

Location of an Emergency Eyewash Station

Ideally, the emergency eyewash station should be located as near the hazard (lab bench or hood) as possible without protruding into the egress path of a workspace. ANSI recommends a location within 10 seconds (100 ft.) of the hazard. An employee should not have to open a door or travel stairs to reach an emergency eyewash station. No one in pain, and possibly blinded, should have to overcome any additional impediments or obstacles in seeking relief. An emergency eyewash station should be centrally placed in a laboratory along a normal path of egress.

Approved Emergency Eyewash Stations

ANSI makes few operational requirements of emergency eyewash stations but insists on proper quality and quantity of water to flush eyes. Flow rates are described in the new standard (ANSI standard Z358·1). The emergency eyewash station must be easily operated, come to full flush rate within one second of activation and remain on until deactivated.

A drench hose which consists of a spray nozzle connected to a flexible hose is not a bad supplement but can not be used in lieu of a proper eyewash. Likewise, squeeze bottles filled with isotonic solutions can offer good initial flushing but will not take the place of an emergency eyewash station.

Other Requirements

Caps shielding eyewash outlets from contamination must not require a separate action to remove before activating the eyewash. If possible, connect the eyewash to a water control valve to issue lukewarm water (90°-95° F). Test the eyewasher on a weekly basis to ensure proper function and prevent growth of organisms in stagnant water lines. All emergency eyewash stations must be identified with highly visible signs which are available through laboratory safety catalogs.

A permanently installed emergency eyewash station is essential in or near every laboratory that uses chemicals. If one is not available, any source of potable water, as long as it is not too hot or too cold, should be used in an emergency. A sink faucet, shower or even a large basin of water can be used for a stricken co-worker. As always, workspace supervisors must inform new staff members on the operation of emergency eyewash stations.

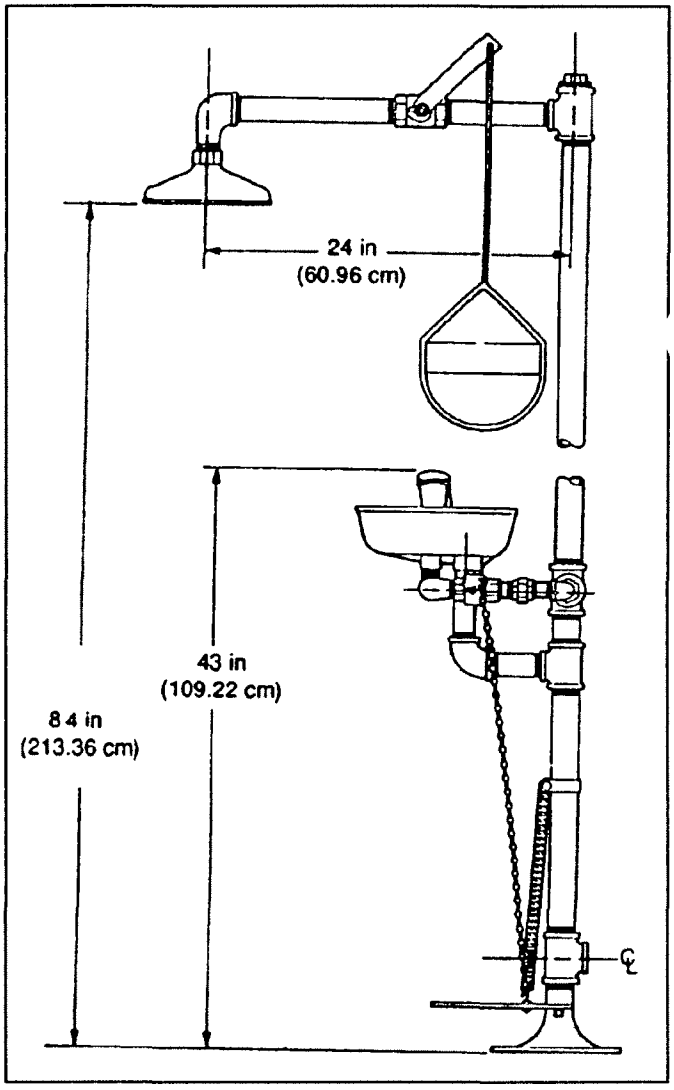

Figure 1. Mounting requirments of an emergency eyewash (shower) station

COPYRIGHT STATUTE DEFINES WORK OF THE U.S. GOVERNMENT

by A. David Spevack

The following is a guide for determining whether a work was prepared as part of an employee's official duties.

1. Preparation of the work was within the employee's position description.
2. Preparation of the work was properly assigned by the employee's superior.
3. The employee was in a position to self-assign the official duty of preparing the work, and it was so self-assigned.

If an employee uses Government time, facilities, equipment, materials, funds, or the services of other Government employees on official duty, the work is considered property of the U.S. Government even if the employee prepared it on personal time and at personal expense.

An employee may be authorized to prepare a work which relates to official duties for incorporation in a non-Government work, such as a book, journal, audiovisual work, sound recording, etc. The work may be done during regular working hours, using Government personnel and facilities, provided it is determined at the appropriate Command level that the preparation and publication of the employee's work will be in Command's interest. In such a situation, the work will be considered a U.S. Government work, not subject to copyright protection in the United States.

An employee would not be prevented from securing copyright in a work prepared clearly outside of official duties, even though the work includes knowledge or information derived from the employee's official duties or relates to the professional field of the employee. Employees should, however, be aware of applicable provisions of the Standards of Conduct for Navy employees with regard to official duties and use of information obtained from official duties.

In situations where it is not clear that the work is outside the employee's official duties but there was a Government contribution in connection with the preparation of the work then the work may be considered to have been prepared as part of the employee's official duties. Copyright protection is not available unless the Government contribution was too insignificant to support a conclusion that the work was prepared as part of the employee's official duties.

CRDA, COOPERATIVE AGREEMENTS, GRANTS, AND PROCUREMENT CONTACTS

The demand for assistance in preparing and getting approval for Cooperative Research and Development Agreements (CRDA) has been overwhelming. For those of you not familiar with them, a CRDA is an agreement specifically provided for under the Technology Transfer Act which permits the Government to receive money, materials, labor, etc. from a collaborator, and give the collaborator materials, labor, etc., but not money. NMRDC and the laboratories have used CRDAs for things as simple as providing university personnel access to specific unique Government equipment. We have submitted so many CRDAs that the combined NMRDC laboratories lead all other laboratories in the Navy in the number of agreements approved and operating.

A CRDA is supposed to be used in those cases where the Government has some unique technology such as knowledge, a new invention, unique equipment, or special skills, which would benefit the US economy if it were transferred to companies which would manufacture, use or produce the results of the collaborative research. A CRDA cannot be combined with a procurement contract because that would violate the requirements not to provide the collaborator with money. The question of what acts constitute providing the collaborator with money can be rather complex. Questions should be direct to Counsel. A CRDA should not be used in place of a standard Federal Acquisition Regulation (FAR) contractor negotiated contract. There are other tools for getting what you need:

1. **Contracts**: Contracts are used for the acquisition of supplies or services to the direct benefit the Federal Government. For example, analytic services, glassware or a particular drug available on the open market are bought through a procurement contract or R&D standard contract.
2. **Grants**: A Grant is used when the principal purpose of the transaction is to stimulate or support R&D for another public purpose. In a Grant, it is not expected that there be any substantial involvement by the agency.

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CURRENT STATUS ON FUNDING/MANPOWER

by CAPT R.W. Gaugler, Executive Officer

The current status of the FY93 and FY94 Funding and Manpower budgets may be best characterized by the phrase *no news is good news.*

As a result of the now famous decision by the Under Secretary of Defense, a substantial portion of our funds have been shifted to the sponsorship of the Office of the Assistant Secretary of Defense, Health Affairs. Although it will greatly complicate our accounting and administrative processes at headquarters, the transfer is moving rapidly toward full implementation at the start of FY93. If all continues to go as planned, there should be little change or even awareness at the laboratory level.

CRDA ETC.

3. **Cooperative Agreements** (not to be to confused with CRDA): The principal purpose is the same as for a Grant, but substantial involvement is expected by the agency in carrying out the activity.

Contracts, Grants and Cooperative Agreements are issued by contracting officers and fall under the FAR. Cooperative Agreements, Grants, and Procurement Contracts usually have only the standard patent clauses which essentially leave rights with the contractor. CRDAs which allows an advance grant of a license and involvement of the Government inventors in the project, falls under the Federal Technology Transfer Act. If you have any questions regarding the different forms of contracts or the best way to accomplish a specific project call Counsel.

The change has, however, provided us with some unexpected benefits, and has the potential for solving our longstanding disagreement with the Army on the management of the infectious disease program. One of the unexpected consequences of the transition has been that the budgetary scrutiny that normally occurs at this time of year has been overcome by the need to ensure that all aspects of the transition are fully and correctly accomplished. The responsible offices at Health Affairs are in the process of determining how program evaluation and budget decisions will be made in the future, leaving the current budget year essentially as originally programmed by the Services.

Meanwhile, the Navy appears to be following the previously announced plan to protect the tech base research programs and absorb any reductions in the acquisition portion of the budget. Our budgets for FY93 and FY94 are essentially unchanged from the FY92 levels, with some selected increases due to the successful efforts of Naval Submarine Medical Research Laboratory in the recent FY94 ATD competition.

The area of greatest uncertainty is the Infectious Disease Program where our interactions with the Army under the new Health Affairs sponsorship remain unclear. A significant part of our funding for the last two years in infectious disease has come from Congressional direction. The Army considers these Congressional directions to be separate from their normal program plans, and in the absence of specific Congressional action, has indicated they will revert to their planned program for the Navy. This program is about half of our actual FY92 expenditure level. We are currently in the midst of revising the ASBREM charter and determining the processes that will be followed in allocating funds under Health Affairs sponsorship. Creating an equitable process for providing unified, tri-service planning in the infectious disease program is first priority in this effort.

On the manpower front, one major difficulty with respect to personnel is that we now have more civilian personnel on board than our man-year ceiling allows. This difficulty is compounded by the fact that our out year funding projections do not match the downward trend that is being used to define the man-year allocations by higher authority. We are scheduled to have our civilian personnel man-years and payroll ceiling reduced six man-years in FY93 and an additional four man-years in FY96. However, these reductions are from a total of 742 man-years, reductions far smaller than the 20% reductions in civilian personnel being programmed for DoD as a whole.

The reversal of the large military billet reductions that had been given to us for FY94-97 are being addressed in the Health Affairs POM submission, where as a result of the sponsorship transfer, it has a greater chance of success. We are confident that the billets will be restored when the process is completed in August 1992.

These trends may be altered in the Congressional actions on the 1993 Budget, or in DoD's formulation of the 1994 Budget to be submitted to Congress next January; but *for now, no news remains good news.*

MANUSCRIPT CLEARANCE POLICY

There have been some questions recently regarding the current process for the clearance of manuscripts generated at the laboratories, and specifically, questions regarding who has the authority for clearance of certain types of publications. In general, under NAVMEDCOMINST 5721.1C and the specific delegations of clearance we have received, the vast majority of manuscripts will normally be given final clearance by the local laboratory Commanding Officer.

Copies of cleared publications should be forwarded through the Naval Medical Research and Development Command to the BUMED Public Affairs Office (MED-OOP). Only four type of publications require clearance at a higher level than the local command.

HIV Manuscripts

All publications dealing with HIV must be forwarded through the Chain of Command to the BUMED Public Affairs Office (MED-OOP) for clearance approval. The BUMED Public Affairs Office (MED-OOP) will coordinate the review through the HIV Program Office, and provide a formal letter of clearance.

Foreign Publications

All manuscripts intended for publication in a foreign country must be cleared at NMRDC.

Manuscripts intended for foreign publications fall under the foreign disclosure regulations of DoD. We have successfully convinced the BUMED Public Affairs Office (MED-OOP) and the DoD Public Affairs Office that, in the medical field, there is little distinction between a foreign and US published journal with respect to the distribution of the information. However, DoD has only been willing to permit delegation of the clearance to the NMRDC level.

Non-Human Primate, Dog, and Cat Research Manuscripts

All publications which describe research involving non-human primates, dogs, or cats as subjects must be cleared at NMRDC. BUMED regulations require that reports of work using these species be reviewed by their Special Assistant for Veterinary Medicine before publication. However, since that individual is double-hatted with NMRDC's Assistant for Veterinary Medicine, the review and clearance actually is accomplished at NMRDC.

Sensitive or Controversial Manuscripts

All publications that may deal with subjects of special sensitivity, as defined in NAVMEDCOMINST 5721.1C, must be approved by the BUMED Public Affairs Office (MED-OOP). These subjects include policy issues, subjects which are potentially or inherently controversial, or those which may be highlighted by media coverage or publicity. If there is any question whether a paper falls in this category, it should be forwarded to BUMED for clearance.

"OPEN FILE" DEPARTMENT OF LEGAL MEDICINE OFFERS CME CREDIT

For two decades, the Department of Legal Medicine of the Armed Forces Institute of Pathology (AFIP) has provided continuing medical education (CME) in risk management and quality assurance. Until now, this function has been performed through field symposia and other educational presentations to physicians in all three Services.

Recently, "OPEN FILE", the Department's publication was redesigned to facilitate this educational function. By completing the medical legal quiz in each issue, readers will earn a total of 5 CME credit hours annually. Physicians licensed in Massachusetts and Florida should be particularly interested in this material, as license renewal in these states requires CME credit in risk management.OPEN FILE has been endorsed by the Quality Assurance representative of each service and a broad mailing effort to all Department of Defense physicians has been initiated.

Requests for copies as well as comments regarding contents of OPEN FILE may be directed to: AFIP-CPY Department of Legal Medicine, Building 54, 14th & Alaska Avenue NW, Washington, DC 20306-6000. Autovon 291-5176 Commercial 301-427-5176.

WINNING AN ATD: PREPARATION AND LUCK

by CAPT P.K. Weathersby and Dr. T.E. Hanna, NSMRL

If your lab is like ours, ATD used to sound like another acronym you heard about once, and were pretty sure it didn't apply to you. We have recently learned that it can. This article recounts how we came to recalibrate our ideas about ATDs.

Last May the Office of the Chief of Naval Research (OCNR) issued a call for the most promising high-risk technology demonstrations, proposals having exceptional technical merit with strong potential for transition.

Throughout the Navy over 1000 proposals were assembled and sent to higher echelons to compete for a slot in the OCNR competition. Submissions to the Office of Advanced Technology (OAT) and OP-91 in September were under a quota system. Major OPNAV codes (including medical at OP-93) could prioritize and submit up to eight Advanced Technology Demonstration (ATD) proposals to OP-91. ONT could send in 25. The format was rigid (three pages max) and, of course, different from any other format used in NMRDC labs for any other type of proposal.

Brief experience as purely spectators in the 1990 competition made us wary of proposals with any weaknesses.

At that time the final review panel seemed to immediately find a seam, insert several knives, and effect a kill in minutes.

Fortunately we started with a good idea. Several (classified) NSMRL auditory techniques at different levels of development could be bundled into a sea-going prototype sonar under advanced development at a "big-sister" laboratory, the Naval Underwater Warfare Center (NUWC) Newport, RI.

Our first step was nearly our last. Accustomed to working in an unclassified medical environment we laundered the proposal until it was UNCLAS but nearly incomprehensible.

After a number of (barely) UNCLAS phone calls, and several more direct meetings, the proposal left NMRDC (acting on behalf of OP-093) as the top priority medical submission. We also tried to get the proposal submitted from our main-line sponsor for sonar work (OP-22) but found later that our naivete in that office led to the proposal being cubbyholed.

During October we continued to learn the ropes both at home in Groton, CT and away in Washington, DC. We heard that the semifinals of the ATD competition occurred in meetings at OP-091 and OAT to cut the 100+ entries to about 30. We therefore arranged to brief the work at OP-091 to get useful advice. One sample exchange: "Why wasn't this work planned under our regular funding?"; right answer: "The idea is too recent to have been POM'd two years ago".

Next we invited an Associate Director of the Office of Advanced Technology (OAT) to visit us and receive the trial briefing and some audio demos. (During this period, briefing slides and demo selections seldom survived a week without revision.)

We also managed to corner the OP-093 voting member on ATDs (CAPT Chaput), and worked the OP-02 connection again. Time and energy expired before we could try to further "stack the deck" at OP-01 and NAVSEA. Somehow we made it through this semifinal round, and we never found out why or how close.

During this time we never did discover a rule book for the whole ATD game. To this day we are unable to furnish a "wiring diagram" for the Navy offices involved in the process. The closest thing to a medical mole in the process was CAPT Larry Dean, MSC, under his OP-911F hat, who was very helpful.

Tournament finals were presentations to the Scientific and Technology Working Group (STWG) composed of senior scientists and operators from OPNAV (OP-01, -02, -03, -04, -05, -07, -08, -094, -091, -093, -096: see your DoD telephone directory for details), and the four SYSCOMS, ONR, ONT, OAT.

When the Thursday afternoon arrived for the presentation before the famous razor-tongued STWG, we arrived in force: a briefing officer, a CO, a principal investigator, a NUWC collaborative investigator, a sonar operator/classified materials custodian, and program managers from OP-02 and NMRDC. After the prepared material came the first question: "Isn't this technology applicable to other Navy problems?". The briefing officer, in full defensive posture, was able to answer, "Yes, sir". Period.

Other STWG member started to supply fuller answers themselves, until time was exhausted. Our usual strategy of keeping a proposal tight and focused had been attacked! Omission of another possible technology under development at NOSC (San Diego), and failure to provide neat answers to Navy needs other than submarine sonar were described as weaknesses.

NSMRL WINNING ATD:
Enhanced Auditory Interface for Transient Acoustic Processing

There is a need in the Navy for improved classification capabilities on submarine passive sonar systems. The TAP ADM auxiliary sonar system, being developed at the Naval Underwater Warfare Center (NUWC), will play a critical role in meeting this need for passive classification of sonar contacts.

In order to provide an effective interface to the sonar operator, attention is being given to human performance issues early in the system development. The Naval Submarine Medical Research Laboratory (NSMRL) has developed several signal-processing techniques that improve the auditory performance of sonar operators. The benefits of the techniques include improved detectability, improved classification, reduced operator fatigue, and decreased interference from other sounds. In addition, two methods of "multiplexing" information to the sonar operator have been examined so that a sonar operator can monitor multiple channels in order to increase the auditory information rate. These new techniques and methods will be incorporated into a TAP ADM prototype to improve sonar operator performance.

Incorporation of NSMRL's techniques into an advanced hardware development program, such as TAP ADM, provides an excellent opportunity to evaluate and modify performance-enhancing capabilities early in the engineering design/ development cycle so that these capabilities will be implemented in the mature system. The auditory interface developed from this project could be used in other sonar systems as well.

The principal effort of the ATD will be to incorporate the techniques developed and evaluated in the laboratory by NSMRL on the TAP ADM prototype for evaluation at sea. The project will provide hardware specifications for auditory presentation methods that significantly improve operator performance on the TAP ADM system.

A risk-reducing facet of this development is to determine performance interactions between different techniques that would limit their joint application and to determine functional limits at sea. These conclusions reduce the extent of hardware modification needed to optimize performance compared with attempts to introduce these techniques as retrofits, a procedure which is expensive for even minor modifications.

At the request of the STWG , prototype demonstrations will be provided to certain other Navy communities. Aviation and surface sonar tasks are natural candidates. Some other cluttered acoustic environments involving ESM and voice communications are also strong contenders. If we can figure out how, entree will be sought to the training and intelligence folks as well.

Winning an ATD (cont.)

We were sent away to redo the game plan and present the new one in 5:00 min (3 slides max) first thing Tuesday morning.

With one of us in Groton and the other in Bethesda (preparing for the serenity of the Strategic Planning Retreat), considerable phone and FAX costs were incurred. Tuesday found the briefing officer, now alone, flashing newly learned acronyms to the sagely nodding audience. The additional $1M + per year did not raise an eyebrow.

Questions and even more suggestions pushed the time to over 9 min. The PI still owes the briefing officer reimbursement for an Arlington, VA, parking ticket. Our final rating was 3rd, well up in the funded group.

We had talked our way into the big league: a new $7.5M over 3 years!

Our advice to other wanna-be contestants is: *Make sure you have a good idea, test market the idea as much as possible, and be prepared for anything from the STWG.*

HIGHLIGHTS OF NMRDC RESEARCH

FDA LICENSURE SOUGHT FOR EXTENDED STORAGE OF SEVERAL FROZEN BLOOD PRODUCTS

Blood products for the resuscitation of severely injured combat casualties are essential for emergency medical care. The logistical difficulties of providing fresh blood products in the initial days to weeks of a military conflict are overwhelming. The alternative to fresh blood products is the appropriate storage and utilization of frozen blood products. NMRDC funded researchers at the Naval Blood Research Laboratory, Boston University School of Medicine, are working with the Blood Bank at the National Naval Medical Center, Bethesda, MD to prepare data for FDA licensure to extend the storage of several frozen blood products. This includes data to support extended storage of fresh frozen plasma and cryoprecipitate at -80°C for at least 3 years (current FDA regulations allow for the storage of fresh frozen plasma and cryoprecipitate for one year at -20°C); storage of frozen single-donor apheresed platelets with 6% DMSO at -80°C for two years(the FDA has approved DMSO as a cryoprotectant for platelets); expanded post-thaw storage of deglycerolized red blood cells in a sodium chloride-glucose solution at 4°C for 7 days and in Optisol, ADSOL or Nutricel solutions at 4°C for 14 days. Another work effort that is part of the above projects is the development of a post thaw red blood cell wash system which is completely closed to the environment. Also, in 1992 the Naval Blood Research Laboratory will begin to assay solutions made by the Resuscitation Fluid Production System (REFLUPS) to provide data to support FDA licensure.

NMRI'S ENTERIC DISEASE PROGRAM TRANSITIONS PROTOTYPE CAMPYLOBACTER VACCINE INTO ADVANCED STAGES OF DEVELOPMENT

Campylobacter jejuni is recognized worldwide as a major bacterial cause of enteric disease and is the second most common cause of bacterial diarrheas in the developing world, accounting for an estimated 400,000,000 cases annually. In the U.S., campylobacter isolations are more frequent than Salmonella and Shigella isolations combined. Researchers in the Campylobacter Research Program at the Naval Medical Research Institute (NMRI), Bethesda, MD, have developed two classes of oral vaccine candidates. One is a stable, live flagellar mutant which immunizes against wild type organisms without colonizing long enough to initiate disease. The second and most advanced, is a killed whole cell preparation with the immunogenicity enhanced by a prototype oral adjuvant. The adjuvant used in this vaccine candidate is also a Navy (ONR) developed product and its utilization in this first generation campylobacter vaccine represents a new concept in enteric vaccine development. In a variety of animal models, the killed whole cell vaccine has no significant side-effects, is highly immunogenic and capable of stimulating protective levels of immunity comparable to that achieved following infection with live organisms. This vaccine may be available for phase I and II safety and immunogenicity testing in human volunteers during early FY93.

RESEARCHERS DEVELOPING FREQUENCY AGILE LASER EYE PROTECTION FOR AIRCREW PERSONNEL

Current laser eye protection protects against one, or several discrete wavelengths of laser radiation. Lasers presently under development will have the capability for either preset or frequency adjustment during operation. These "agile" lasers require a conceptually different type of eye protection. In 1986, a multi-service, multi-disciplinary team of experts brought together by the Vision Laboratory of the Naval Air Development Center, Warminster, PA, and funded in part by NMRDC, began investigating various nonlinear optical materials. This group has been working to develop new technologies to ensure that eyes will not be damaged and vision will not be disrupted when aircrew personnel are irradiated by a frequency agile laser. To be effective the new eye protection system must respond across the visible spectrum, activate in less than a nanosecond, remain in the closed state until cessation of radiation, have a minimum unactivated state transmittance of 75%, and be able to withstand high peak incident powers. Presently, three technology demonstrators are being fabricated based on liquid suspension and liquid crystal technologies. Recent field tests conclusively demonstrated that the liquid suspension cell functions well in the presence of atmospheric scintillation which can cause significant restructuring of the power profile of the incident laser. Testing is underway to begin transition of the most promising technologies in addition to pursuing five additional technologies.

For more information on NMRDC research projects contact NMRDC Code 04, 301-295-1468 or 301-295-0833

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