NORTH ATLANTIC TREATY ORGANISATION

RESEARCH AND TECHNOLOGY ORGANISATION

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RTO TECHNICAL REPORT **TR-HFM-130**

Development of an Assessment Methodology for Demonstrating Usability, Technical Maturity, and Operational Benefits of Advanced Medical Technology

(Développement d'une méthodologie d'évaluation permettant de démontrer la facilité d'utilisation, la maturité technique et les avantages opérationnels des technologies médicales évoluées)

Final Report and Recommendations to NATO of Task Group HFM-130.

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The Research and Technology Organisation (RTO) of NATO

RTO is the single focus in NATO for Defence Research and Technology activities. Its mission is to conduct and promote co-operative research and information exchange. The objective is to support the development and effective use of national defence research and technology and to meet the military needs of the Alliance, to maintain a technological lead, and to provide advice to NATO and national decision makers. The RTO performs its mission with the support of an extensive network of national experts. It also ensures effective co-ordination with other NATO bodies involved in R&T activities.

RTO reports both to the Military Committee of NATO and to the Conference of National Armament Directors. It comprises a Research and Technology Board (RTB) as the highest level of national representation and the Research and Technology Agency (RTA), a dedicated staff with its headquarters in Neuilly, near Paris, France. In order to facilitate contacts with the military users and other NATO activities, a small part of the RTA staff is located in NATO Headquarters in Brussels. The Brussels staff also co-ordinates RTO's co-operation with nations in Middle and Eastern Europe, to which RTO attaches particular importance especially as working together in the field of research is one of the more promising areas of co-operation.

The total spectrum of R&T activities is covered by the following 7 bodies:

- AVT Applied Vehicle Technology Panel
- HFM Human Factors and Medicine Panel
- IST Information Systems Technology Panel
- NMSG NATO Modelling and Simulation Group
- SAS System Analysis and Studies Panel
- SCI Systems Concepts and Integration Panel
- SET Sensors and Electronics Technology Panel

These bodies are made up of national representatives as well as generally recognised 'world class' scientists. They also provide a communication link to military users and other NATO bodies. RTO's scientific and technological work is carried out by Technical Teams, created for specific activities and with a specific duration. Such Technical Teams can organise workshops, symposia, field trials, lecture series and training courses. An important function of these Technical Teams is to ensure the continuity of the expert networks.

RTO builds upon earlier co-operation in defence research and technology as set-up under the Advisory Group for Aerospace Research and Development (AGARD) and the Defence Research Group (DRG). AGARD and the DRG share common roots in that they were both established at the initiative of Dr Theodore von Kármán, a leading aerospace scientist, who early on recognised the importance of scientific support for the Allied Armed Forces. RTO is capitalising on these common roots in order to provide the Alliance and the NATO nations with a strong scientific and technological basis that will guarantee a solid base for the future.

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Abbreviations, Acronyms, Definitions and Terms

ACO	Allied Command Operations
ACT	Allied Command Transformation
ACTD	Advanced Concept Technology Demonstration
AFI	Air Force Instruction (USA)
AFMAN	Air Force Manual (USA)
DoD	Department of Defense (USA)
DoDD	Department of Defense Directive (USA)
DR	Deficiency Report or Deficiency Reporting
EPOW	Experimentation Programme Of Work
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
KPP	Key Performance Parameters
KSA	Key System Attributes
MOE	Measure Of Effectiveness
MOP	Measures Of Performance
MTD	Medical Technology Demonstration
NAMSA	NATO Maintenance and Supply Agency
NATO	North Atlantic Treaty Organisation
NTO	NATO Test Organisation
OT TC	Operational Test Test Concept
OT&E	Operational Test and Evaluation
OTRR	Operational Test Readiness Review
SPOW	Scientific Program Of Work—Term now changed to EPOW
T&E	Test and Evaluation
TEMP	Test and Evaluation Master Plan
TRL	Technology Readiness Level

DEFINITIONS/TERMS

Advanced Concept Technology Demonstration – A demonstration of the military utility of a significant new technology and an assessment to clearly establish operational utility and system integrity. Within the NATO context and for the purposes of this document, this term has been modified to Medical Technology Demonstration (MTD).

Capability Based Testing – A mission-focused methodology of verifying that a capabilities solution will enable operations at an acceptable level of risk. Capabilities-oriented evaluations are emphasized throughout system testing in addition to traditional evaluations of system performance measured against specification-like requirements. It requires understanding Concept of Operations and involves developing T&E strategies and plans to determine whether a capability solution option merits fielding.

Critical Operational Issue (COI)

1) Operational effectiveness and operational suitability issues (not parameters, objectives, or thresholds) that must be examined during operational testing to determine the system's capability to perform its mission.

2) A key question that must be examined in operational test and evaluation to determine the system's capability to perform its mission. Testers normally phrase a COI as a question to be answered in evaluating a system's operational effectiveness or suitability.

Compatibility – The suitability of products, processes or services for use together under specific conditions to fulfill relevant requirements without causing unacceptable interactions. (AAP-6)

Deficiency Report (DR) – The report used to identify, document, and track system deficiency or enhancement data while a system is in advanced development, operational test, or operational transition.

- **Category I** – DRs are those which could cause death, severe injury, severe occupational illness, major loss or damage, or directly restrict combat or operational readiness if left uncorrected.
- **Category II** – DRs are those which do not meet the criteria of a Cat I DR. They are attributable to errors in workmanship, non-conformance to specifications, drawing standards, or other technical requirements; or identify a problem for potential improvement or enhancement.
- **Enhancements** are a type of Category II DR which identifies conditions that complement, but are not absolutely required for successful mission accomplishment. The recommended condition, if incorporated, will improve a system's operational effectiveness or suitability.

Key Performance Parameters – Required system capabilities. If not met, the device/system fails the test and evaluation and is deemed non-deployable.

Key System Attributes – Capabilities that are desired, but not required for deployment/utilization.

Measures Of Performance (MOP) – Testable and measurable attributes of the performance which can be evaluated by a T&E process.

Operational Test and Evaluation (OT&E)

1) The field test, under realistic combat conditions, of any item of (or key component of) equipment for the purpose of determining the effectiveness and suitability of the equipment for use in combat by typical military users; and the evaluation of the results of such test.

2) Testing and evaluation conducted in as realistic an operational environment as possible to estimate the prospective system's operational effectiveness and operational suitability. In addition, OT&E provides information on organization, personnel requirements, doctrine, and tactics. It may also provide data to support or verify material in operating instructions, publications, and handbooks.

Operational Testing – A generic term describing the test and evaluation options and levels of effort available to an operational test organization.

Oversight – Senior executive-level monitoring and review of programs to ensure compliance with policy and attainment of broad program goals.

Test and Evaluation (T&E) – The act of generating empirical data during the research, development or sustainment of systems, and the creation of information through analysis that is useful to technical personnel and decision makers for reducing design and acquisition risks. The process by which systems are measured against requirements and specifications, and the results analyzed so as to gauge progress and provide feedback.

Test and Evaluation Master Plan (TEMP) – Documents the overall structure and objectives of the T&E program. It provides a framework within which to generate detailed T&E plans and it documents schedule and resource implications associated with the T&E program. The TEMP identifies the necessary developmental, operational, and live test activities. It relates program schedule, test management strategy and structure, and required resources to: COIs; critical technical parameters; objectives and thresholds documented in the requirements document.

Test and Evaluation Organization – Any organization whose designated mission includes test and evaluation.

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Development of an Assessment Methodology for Demonstrating Usability, Technical Maturity, and Operational Benefits of Advanced Medical Technology

(RTO-TR-HFM-130)

Executive Summary

Many nations, both within the Alliance and those of the Partnership for Peace, have in recent years developed various modalities of advanced medical technologies for operational field use. These range from classic teleconsultation through biosurveillance systems and distance education to information management systems for maintaining medical awareness of the battlefield, and most recently the concept of the use of Unmanned Aerial Vehicles (UAVs) for casualty evacuation (CASEVAC). Some of these groups of technologies may include real-time soldier/patient status monitoring, patient tracking, medical logistics status monitoring, and epidemiological reporting. The Allied Command Operations Medical Advisor has determined that these advanced technologies can potentially be of great benefit as a medical force multiplier, and has requested that telemedicine in this broader sense be incorporated into the medical support structures for the NATO Response Force. The importance of these developments is clearly shown by the continuing RTO efforts to identify and evaluate such technology (e.g., RTG-182, "Use of Advanced Technologies and New Procedures in Medical Field Operations" and RTG-184, "Safe Ride Standards for Patient Evacuation Using Unmanned Aerial Vehicles (UAVs)"). However, to date there is no standardized approach to evaluate under test circumstances the operational benefit and functionality of these new technologies.

Many of these technologies are being fielded at the national level, based on a national "gestalt" that potential benefits of their use are obvious. Unfortunately, adoption of any particular technology or telemedicine modality for Alliance support is hindered by the lack of any standardized NATO assessment mechanism which can evaluate and assess new medical technologies for technical maturity, usability (in the classic human factors sense), and benefits to the patient, the clinician, and the operational commander. Development of such an evaluation mechanism could lead to increased deployment of such advanced medical technologies, as well as increased interoperability. Widespread deployment of such technologies during multi-national NATO operations would have obvious potential benefit in reducing morbidity and mortality, allowing a reduced medical "footprint" in the operational area, and in allowing the NATO Theatre Surgeon and the Operational Commanders to maintain an improved understanding of the medical status of their deployed forces and the deployed medical support structures. The availability of a standardized assessment and evaluation methodology could significantly assist in the decision-making as to whether or not to field such new technology in the multi-national environment.

RTG-130 has examined the various mechanisms currently in use by various nations to test the field usability of such devices, and has carefully examined the world literature on Health Technology Assessment and Medical Equipment Testing. We have also analyzed the current exercise and material-testing programs of NATO to determine how such testing could potentially be inserted into currently-existing programs. A schema for using the concept of Technology Readiness Levels (TRLs) in the evaluation of biomedical developments has been developed and recommended for formal NATO adoption and use. Finally, a proposed test procedure/process for evaluation and testing of future such developments for use within the NATO multi-national environment has been developed, which recommends assignment of this task to the Medical Branch at Allied Command Transformation (ACT).

Développement d'une méthodologie d'évaluation permettant de démontrer la facilité d'utilisation, la maturité technique et les avantages opérationnels des technologies médicales évoluées

(RTO-TR-HFM-130)

Synthèse

Nombre de nations, que ce soit au sein de l'Alliance ou dans le cadre du Partenariat pour la paix, ont développé au cours des dernières années diverses modalités relatives aux technologies médicales évoluées et à leur utilisation sur le théâtre des opérations. Elles varient de la téléconsultation classique via les systèmes de bio-surveillance et l'enseignement à distance, aux systèmes de gestion de l'information visant à maintenir une vigilance médicale sur le champ de bataille, en passant plus récemment par le concept d'utilisation de Véhicules aériens sans pilote (UAV) pour l'évacuation des blessés (CASEVAC). Certaines de ces technologies peuvent inclure en temps réel le contrôle de l'état du combattant/patient, la localisation du patient, le contrôle de l'état de la logistique médicale, ou encore l'établissement de rapports épidémiologiques. Le Conseiller médical du Commandement allié pour les Opérations a conclu que ces technologies évoluées pourraient apporter un bénéfice considérable en démultipliant les forces médicales, et a demandé que la télémédecine dans son acception la plus large soit incorporée dans les structures de soutien médical de la Force de réaction de l'OTAN. L'importance de ces développements est clairement démontrée par la poursuite des efforts de la RTO en vue d'identifier et d'évaluer ces technologies (RTG-182 : « Utilisation de technologies évoluées et de nouvelles procédures dans les opérations médicales de campagne », RTG-184 : « Normes de sécurité pour l'évacuation des patients à l'aide de Véhicules aériens sans pilote (UAV) », etc.). Toutefois, il n'existe à ce jour aucune approche standardisée permettant d'évaluer par des essais les bénéfices opérationnels et la fonctionnalité de ces nouvelles technologies.

Plusieurs de ces technologies sont utilisées sur le terrain au niveau national, en se fondant sur l'a priori selon lequel les bénéfices potentiels apportés par leur mise en œuvre sont évidents. Malheureusement, l'absence d'un mécanisme d'évaluation standardisé de l'OTAN, capable de déterminer la maturité technique, la facilité d'utilisation (au sens classique des facteurs humains) et les bénéfices de ces nouvelles technologies médicales pour le patient, le clinicien et le commandement opérationnel, empêche l'adoption d'une technologie ou d'une modalité de télémédecine particulière pour le soutien de l'Alliance. Le développement d'un tel mécanisme d'évaluation pourrait permettre d'accroître le déploiement de ces technologies médicales évoluées, ainsi que l'interopérabilité. Le déploiement généralisé de ces technologies lors d'opérations multinationales de l'OTAN générerait un bénéfice potentiel évident, permettant de réduire la morbidité et la mortalité, de limiter « l'empreinte » médicale dans la zone opérationnelle, et procurant au Médecin-chef du théâtre et aux Commandants opérationnels de l'OTAN une meilleure connaissance de l'état médical de leurs forces et des structures de soutien médical déployées. La mise à disposition d'une méthodologie d'évaluation standardisée pourrait faciliter considérablement la prise de décision quant à l'utilisation ou la non-utilisation de ces nouvelles technologies dans un environnement multinational.

Le RTG-130 a examiné les divers mécanismes actuellement mis en œuvre par plusieurs nations, en vue de tester la facilité d'utilisation de ces dispositifs sur le terrain; il a en outre soigneusement étudié la documentation internationale disponible sur l'évaluation des technologies médicales et les tests réalisés

sur le matériel médical. Nous avons également analysé les programmes actuels de l'OTAN relatifs à l'essai du matériel et aux exercices, en vue d'établir dans quelle mesure de tels essais pourraient être inclus dans les programmes déjà existants. Un schéma d'utilisation du concept de Niveaux de maturité technologique (TRL) lors de l'évaluation de développements biomédicaux a été conçu et recommandé pour adoption formelle et utilisation par l'OTAN. Enfin, une proposition de procédure d'essai/processus d'évaluation et de test des futurs développements, à utiliser dans l'environnement international de l'OTAN, a été présentée, recommandant l'attribution de cette tâche à la branche médicale du Commandement allié Transformation (ACT).

Chapter 1 – INTRODUCTION

1.1 ESTABLISHMENT OF THE RTG

In 2004, the Human Factors and Medicine (HFM) Panel of the NATO Research and Technology Organization (RTO) established an Exploratory Team, HFM/ET-051, with the mission of examining the topic "Applications and Assessments for Telemedicine (TMED) Support to the NATO Response Force (NRF)". The justification for this ET was that full-spectrum operations of NATO forces (e.g., the "NATO Response Force" (NRF)) must be supported and sustained by the most modern military medical systems and technologies. The emergence of "telemedicine" (TMED) as both an operational domain and a research and development (R&D) discipline is currently being exploited for modernization of NATO medical support capabilities through various activities of the NATO Military Committee (MC) – the COMEDS TMED Expert Team which is heavily involved in developing standards for TMED within the Multi-National Medical Community, and in identifying required changes to NATO policy and doctrine to incorporate TMED into NATO operational medical doctrine.

Throughout 2005, this ET examined the issues, and coordinated with numerous other NATO bodies to determine the most appropriate way ahead toward resolution of this task. Their final recommendation was that two separate RTG Task Groups be established, one of which would examine the concept of Technological Readiness Levels, field experimentation and evaluation of advanced medical technologies within the NATO multi-national environment. It was believed that in order to achieve an understanding of TMED in the NATO operational context, a HFM activity was needed in order to discuss assessments of TMED technology TRLs, to survey of the readiness of NATO support areas to deploy TMED technology, and to determine appropriate opportunities to conduct cooperative technology demonstrations. This recommendation was accepted by the HFM Panel and the RTB, and resulted in the formation of the current RTG-130. The other recommended RTG was expected to look into the concept of testing and evaluation of embedded algorithms within medical systems and devices, and was subsequently organized as RTG-131, which is not a subject of this report.

RTG-130 was formed with a mandate to look at the entire spectrum of advanced medical technology and its evaluation rather than being restricted solely to Telemedicine as was originally envisaged. The implementation of the RTG was delayed for two years, for multiple reasons, but was finally able to start work on this topic in late October of 2006. Due to its late start, a lifespan extension until October 2009 was approved by the RTB. In carrying out its mandate, the RTG met four times as a committee of the whole, with additional work being carried out between meetings.

To support the development of standards and doctrine, there is a need to understand the maturity and efficacy of those technologies that enable the effective provision of field medical care and to assess critical medical technologies using the "Technology Readiness Level" (TRL) assessment methodology. Selected "Cooperative Demonstrations of Technology" (CDT) for support to the NRF and other NATO operational scenarios (such as ISAF) can serve to guide the technology modernization path for the use of advanced technologies in operational medicine. The importance of this effort is demonstrated by the fact that within the past year (2009) an agreement has been reached between SHAPE and the U.S. Army Medical Command to allow NATO-led forces in Afghanistan to utilize the clinical consultation services of the U.S. Army's deployed "AKO" Teleconsultation System, as a field test to demonstrate multi-national feasibility, but without any formal NATO assessment process or system. Establishment of an evaluation process as recommended in this Technical Report would materially assist COMEDS, ACT, and ACO in determining which new medical technologies could effectively enhance NATO multi-national medical care.

RTG-130 has based its work on the following.

1.2 BACKGROUND AND JUSTIFICATION

Many nations, both within the Alliance and within the Partnership for Peace (PfP) program, have in recent years developed various modalities of advanced medical technologies for operational field use. These range from classic teleconsultation through biosurveillance systems and distance education to information management systems for maintaining medical awareness of the battlefield. This latter group of technologies may include real-time soldier/patient status monitoring, patient tracking, medical logistics status monitoring, and epidemiological reporting. One of the most recent proposals is for the use of unmanned aerial vehicles as Casualty Evacuation (CASEVAC) vehicles, and the required development of "safe ride standards" for such aircraft. Such developments are currently the subject of evaluation by RTG-182 and RTG-184, among others. The Allied Command Operations Medical Advisor has determined that these advanced technologies can potentially be of great benefit as a medical force multiplier, and has requested that Telemedicine in its broadest sense be incorporated into the medical support structures for the NATO Response Force and other NATO deployed and deployable forces. These advanced medical technologies are widely seen as having potential benefit to patients, clinicians, and commanders in multi-national operations in a field setting. Many of these technologies are being fielded at the national level, based on a national "gestalt" that potential benefits of their use are obvious, or based on national testing programs. Unfortunately, adoption of any particular technology or telemedicine modality for Alliance operational support is hindered by the lack of any standardized NATO assessment mechanism which can evaluate and assess new medical technologies for technical maturity, usability (in the classic human factors sense), and benefits to the patient, the clinician, and the operational commander. Development of such an evaluation mechanism could lead to increased deployment of such advanced medical technologies, as well as increased interoperability, widespread deployment of such technologies during NATO multi-national operations would have obvious potential benefit in reducing morbidity and mortality, allowing a reduced medical "footprint" in the operational area, and in allowing the NATO Theatre Surgeon and the Operational Commanders to maintain an improved understanding of the medical status of their deployed forces and the deployed medical support structures. The availability of a standardized assessment and evaluation methodology could significantly assist in the decision-making as to whether or not to field such new technology in the multi-national environment.

1.3 OBJECTIVE(S)

The Technical Group was assigned to carry out research aimed at the evaluation of current and proposed test methods to determine technical maturity, usability, and benefit of advanced medical technology (including both hardware and embedded software). A large number of technology assessment concepts were reviewed, including the general concept of Health Technology Assessment (HTA), which was determined to not be suitable in its entirety for NATO use. We discovered that few of our nations have specific programs designed to perform standardized testing and evaluation on advanced medical technology in the field environment. Frequently, it appears that only local testing by potential future users is carried out prior to purchase or adoption, rather than any type of a centralized Test and Evaluation program. We evaluated these existing programs from as many nations as possible. After evaluation of these methods, a suitable "standardizable" method was designed for possible NATO standardization. We propose that this selected method should be tested in the field during a Cooperative Technology Demonstration, which could carry out a field trial/demonstration/assessment of various devices usable at Roles 1/2, using a scenario to be approved by the ACO/ACT Medical Advisors. If successful, the proposed standardized methodology may be considered for publication as a NATO standardization document.

1.4 TOPICS COVERED

The Task Group carried out a historical review of advanced medical technology test and evaluation procedures. It also discussed:

- Operational issues;
- Functional issues;
- Human factors usability issues;
- NATO requirements;
- Operational test and evaluation; and
- Standardization.

Health Technology Assessment (HTA), and all its ramifications were also discussed in detail.

1.5 DELIVERABLE AND/OR END PRODUCTS

The group has produced:

- A set of biomedical Technology Readiness Level (TRL) definitions which are recommended for NATO adoption to guide future considerations for equipment development and acceptance;
- A recommendation for identifying a NATO body which could be tasked with overall responsibility for medical equipment Test and Evaluation (T&E);
- A standardized NATO test and evaluation procedure for Advanced Medical Technology proposed for use in the NATO multi-national medical environment; and
- Several guidelines for use in evaluation of the results of such testing.

Chapter 2 – TECHNOLOGY ASSESSMENT IN THE MEDICAL REALM WITHIN NATO

2.1 THE NEED FOR TECHNOLOGY ASSESSMENT OF MEDICAL TECHNOLOGIES WITHIN NATO

Changes in NATO policies and doctrine highlight the many changes faced by the Alliance in recent years. The Alliance has made numerous strides in adapting to its new role in the world, and medical support is an integral part of this new situation. Whereas in the past medical support was considered a strictly national responsibility, it is now considered a shared responsibility between the contributing nations and the NATO Commander[1,2]. At the same time, the operational concepts have changed to the extent that no longer is it assumed that any one nation will provide the full panoply of Role 1 through Role 4 medical support to any operation. Current NATO doctrine for operational medical support envisions many changes in future medical support structures, including true multi-national medical units, role specialization, host nation support, and increased requirements for interoperability among and between national medical support structures[3].

Thus, the old medical operational concept in which a nation really only had to be primarily concerned with support of its own troops by its own national medical system, with the consequent "simple" requirement for interoperability only within its own system, has evolved. Accordingly, it is critical that any nation desiring to deploy new or advanced medical technology to support NATO operations ensure that its systems are usable by, and are interoperable with, those of other nations.

This change from totally nationally-provided medical services to joint responsibility has been reflected not only in doctrine, but also in organizational structure. The Committee of the Chiefs of the Military Medical Services in NATO (COMEDS – The Alliance's senior medical body), the NATO Standardization Agency, and the Joint Medical Committee have in recent years changed their organizational structures, interrelationships, and working practices to reflect this new reality.

However, the nations still retain the responsibility for maintaining, training, and equipping their own military medical forces. At the present time, NATO neither purchases nor develops medical technology with the exception of the NATO Maintenance and Supply Agency's (NAMSA) current efforts in hospital procurement for Afghanistan. Development and procurement of medical materiel is still a national responsibility. Thus, it is the nations which have always decided if new medical technology is to be adopted for use within their forces, often without full consideration of the impact of this change upon NATO medical support. An old quip is that the only medical equipment items that NATO owns **as an alliance** are the first aid kits on their AWACS aircraft. This is not totally unfounded, as it remains the nations which maintain the responsibility for development, procurement, and stocking of medical materiel. This national responsibility in the logistics field implies that the nations, not NATO, will remain primarily responsible for the development and fielding of new medical support structures and the new technologies which are incorporated therein. This concept may need to change as there is recognized to be more need for standardized NATO medical support structures, which may be reflected in future capability packages, etc. The first steps toward a true alliance capability in this regard might be reflected in the early 2007 creation of a medical cell at the NAMSA and the currently-

[1] MC 319/2.

[2] MC 326/2.

[3] AJP-4.10 (A).

proposed multi-national medical facility at Camp Bastion, Afghanistan. However, until such a change is formally made, the NATO interest in new fielded medical devices and technology is to ensure that these developments:

1) Enhance the overall medical support posture of the Alliance;
2) Perform as intended in the multi-national field environment;
3) Can be effectively incorporated into NATO medical doctrine; and
4) Are interoperable with other national medical systems to the extent needed to enhance multi-national medical care.

At the same time as we are seeing these organizational and operational changes, changes in medical technology are occurring by leaps and bounds. Medical technology is changing rapidly in many key areas, and the speed of development of advanced medical technology has accelerated. Last year's technology may not provide optimum medical support on tomorrow's battlefield, and currently critical technologies may either become obsolescent or develop rapidly. Keeping pace with technology and ensuring that new medical equipment proposed for use within the Alliance meets operational demands will be challenging in the 21st century. Taking full advantage of these advances in medical technology to provide operationally relevant medical care is a critical aspect of the transformation of the Alliance. To take full advantage of these advances in medical technology, NATO must place the best possible medical technology in the hands of the medical personnel who will support future military operations, and must ensure that it operates as intended, that it supports current and evolving NATO medical support doctrine, and that it is usable by personnel and organizations other than those of the developer nations. These demands imply that there is a requirement for operational testing of new medical technologies at the NATO level before new national equipment should be accepted for NATO use in multi-national operations. It is NATO as an Alliance which needs to test the equipment, not for simple medical function, but for its usability and adaptability within the NATO doctrinal structure.

Many if not most of the critical advanced medical technologies are developed and produced by commercial industries rather than defence-related or national facilities, and therefore may be introduced on the commercial market and purchased by the nations without a full consideration of how (or whether) they could be used in the NATO multi-national environment. The different levels of training, language skills, and technological know-how which may be found in different national contributions to a NATO operation are not necessarily recognized by the developers or by national medical authorities. It is therefore critical that NATO develop a policy which can address the issues of usability and compatibility with current and developing doctrine prior to accepting new medical technologies.

We consider that it will continue to be a primarily national responsibility to leverage the best medical technology available, to rapidly transition this technology into new medical systems and force structures, and to propose its use within the NATO environment. However, there is a distinct need for the Alliance to become involved in determining the utility of that technology in supporting current and future medical doctrine, its usability in the multi-national environment, and its potential human factors issues when users come from many Allied and PfP nations with differing levels of medical technological background. Whether or not future doctrine encompasses actual NATO procurement and stockage of medical equipment and supplies, or whether this provision remains a strictly national responsibility, there is a requirement that such equipment be found to be: suitable for its proposed use; usable by all NATO and PfP medical personnel who might have to operate, maintain, or repair it; and coherent with NATO medical doctrine.

Before a new system is fielded, potential operational users should participate in testing and evaluating the operation of the system to ensure that the new system is effective when used under realistic conditions and will meet the required operational need. Thus, there is a perceived need for a NATO Test and Evaluation (T&E) policy for new medical equipment (and the operational concepts which will derive from its adoption) which must be integrated into other NATO T&E programs. There is currently no NATO body which has the mission to support or to carry out this mission.

After a careful inspection of all medically-related organizations within the NATO Alliance, we have come to the conclusion that the only suitable organization to be tasked with such a mission is that of the medical branch at Allied Command Transformation (ACT). Since the real question involved in such T&E is how the introduction of the new medical equipment will fit into or affect NATO doctrine, and since ACT is the organization directly responsible for the development and adoption of new doctrine, it appears evident that testing the suitability of such new equipment and its effects on NATO doctrine most appropriately falls to ACT. ACO is tasked to implement the doctrine, and has input into the development of new doctrine based on operational experience and lessons learned, but it remains ACT's responsibility to actually develop the new concepts and doctrine. NAMSA may undertake the acceptance testing of any medical equipment which NATO decides to purchase in the future to ensure compliance with procurement contracts and functionality, but they do not have the mission or the capability of carrying out or planning the type of operational T&E which we feel is required. We recognize that this new mission assignment might demand increased personnel and budget allocations for ACT. **It must be noted that ACT Medical Section does not agree with this concept of responsibility assignment, though they have no viable alternatives to propose. They are of the opinion that they currently have no tasking for this mission, nor do they have adequate personnel and budget to carry it out. We are in complete agreement, and agree that in order to carry out our recommendation, ACT Medical Branch would need to receive a formal tasking for this mission, and would need to have increased personnel and budget authorized for this purpose. That need, however, does not invalidate our recommendation as to our belief that ACT is the most appropriate body to be given this mission.**

The previous recommendation does not, of course, mean that ACT personnel must have the direct responsibility for carrying out such tests – it simply means that any such testing should be carried out at the direction and under the general supervision of ACT. Such evaluation should be carried out under the authority of ACT, and should be included in its Experimentation Programme of Work (EPOW) or its exercise program. The actual carrying out of the evaluation could be tasked to other agencies as appropriate. ACT already has its work in materiel development (e.g., the MEDICS project) contracted out to NC3A, and in the past the Medical Communications and Information Systems (MedCIS) Expert Panel has carried out development of business process models for various systems on behalf of ACT, as part of the exercise program. In the future, it is possible that the proposed Medical Center of Excellence (Med COE) could undertake some aspects of this work on behalf of ACT. In the realization that NATO may decide not to assign this responsibility to ACT in the future, throughout this document we have referred to the organization responsible for testing new medical equipment as the "NATO Testing Organization" (NTO), to avoid confusion. In spite of that, we do believe that the ACT is the most appropriate organization to be tasked with the responsibility of serving as the NTO.

2.2 HEALTH TECHNOLOGY ASSESSMENT (HTA)

During the first meeting of this RTG, an unspoken assumption was that our task was to develop a Health Technology Assessment (HTA) program for NATO along the lines of those currently in use in several nations and internationally[4]. However, on careful analysis of our task, and after examining the HTA literature,

[4] The Reference List contains many references referring to this concept.

we realized that our task was NOT to develop a NATO Health Technology Assessment program – HTA as normally carried out involves both economic and clinical benefit analysis to assist a health service in making a procurement decision – all we are looking at within NATO are operational benefit and operational usability. While there are certainly aspects of the HTA process which are relevant to this effort (as detailed in the reference list), HTA is fundamentally a research-based, applied assessment of all relevant available knowledge of clinical problems and their potential solutions, including overall clinical benefit and cost-benefit analysis. It is not only an assessment of clinical or operational capabilities, but is also directed at policy-making, and has strong relationships with planning, administration, budgeting, and management due to a focus on decision-making. Thus, HTA not only addresses the issue of "does this technology do what it is supposed to do, and is it both beneficial and usable?", but also the issue of "should our organization adopt this technology from a policy/budget standpoint?" The HTA also takes into account results obtained from randomized controlled clinical and/or epidemiological trials, examining such elements as competing clinical technologies, side effects, and cost-benefit analyses. While of course of interest to those nations considering adoption of these technologies for use within their own national health systems or military medical systems, many of the issues involved in a true HTA are not really relevant to the NATO environment, as one or more of the nations will have already decided to purchase and use this technology before offering it for use in the NATO multi-national medical environment. Thus, our approach has been to look at this issue more along the lines of operational/usability testing than those of a full HTA. NATO simply has no current capability for carrying out full HTA programs (which historically can take 9 – 36 months per analysis[5]), and in doing so would be intruding on national prerogatives to manage their own military health care systems. Thus, we have chosen to not attempt to develop an HTA mechanism for use within the Alliance.

On the other hand, many of the elements and functions of an HTA have direct applicability to the NATO scenario[6,7,8]. The concepts of question development prior to study, and various testing programs, have direct cross-over utility for NATO, even when the final outcome is desired to be less complex than a full HTA.

2.3 TECHNOLOGY READINESS ASSESSMENT (TRA)

A Technology Readiness Assessment (TRA) is one sub-set of the full group of analyses included in a HTA, but is one which also has utility outside of the HTA concept. A TRA can be defined as a systematic and metrics-based process which is used to assess the maturity of certain technologies before moving on to further development or fielding. It can be applied to either devices or to Critical Technology Elements in a system. In our context, it can be considered a pre-screening of new medical equipment to determine whether or not that equipment is technologically advanced enough to enter the below-proposed NATO medical equipment Test and Evaluation system.

Many nations currently use a system called evolutionary acquisition or "spiral development", which enables the rapid fielding of an initial capability to the end-user, followed by new versions with incremental improvements in capability. In the past, many requirements developers established extremely detailed and challenging performance requirements which often resulted in long, high-risk, and expensive development and acquisition programs. Evolutionary acquisition uses more realistic requirements which will enable the

[5] For example, Danish Centre for Evaluation and Health Technology Assessment (DACEHTA); Introduction to Mini-HTA.

[6] For example, Canadian Agency for Drugs and Technologies in Health. Guidelines for the Economic Evaluation of Health Technologies.

[7] For example, Goodman, C., et al. Health Care Technology Assessment in VA.

[8] Kristensen, F.B., Hørder, M. and Poulsen, P.B. (Eds.), Health Technology Assessment Handbook.

rapid fielding of an initial capability to the end-user, followed by new versions with incremental improvements in capability. At the same time that the equipment is being developed and fielded, the government communities for requirements, acquisition, R&D, and sustainment work together as a team along with the technology developer, to refine the details of the system and agree on tradeoffs needed to make the system both more optimally effective and affordable. While a system is being developed, the requirements producers identify the essential capabilities needed but allow the technology developers the flexibility to determine how the need is met. Giving all involved the largest possible flexibility enables innovation and the balancing of performance, operational and support characteristics. Thus, a technology which provides an 80% solution may be fielded and used pending development of the 100% solution, rather than waiting for the 100% solution to become technologically viable.

This system of development is extremely useful and valid when the end-user and the technological developers always work within the same system, but it poses significant potential threats to a system such as NATO. If the end-user is not from the same country as the developer, and if the requirements generator has not taken into account Alliance (as versus strictly national) doctrine, then it is possible that the technology or system which works quite well in the national system of "spiral development" may not be understood or work as well in the context of NATO doctrine.

One central theme of the materiel development process is that the technology employed in system development should be adequately "mature" before system development begins. Normally, for technology to be considered mature, it must have been applied in a prototype article (a system, sub-system, or component), tested in a relevant or operational environment, and found to have performed adequately for the intended application. This implies a need for a way to measure maturity and for a process to ensure that only sufficiently mature technology is employed[9]. In the absence of such a mechanism, it is possible to waste a significant amount of time and money testing equipment or devices which are later found to not be sufficiently technologically advanced for production and deployment. A TRA is a systematic, metrics-based process which assesses the maturity of critical technology elements. The TRA should be conducted before entering a technology into a NATO T&E Program. If a platform or system depends on specific technologies to meet system operational threshold requirements in development, production, and operation, and if the technology or its application is either new or novel, then that technology is considered a Critical Technology Element. The TRA is not a *risk assessment* per se as detailed in Chapter 6, but it should be viewed as a tool for assessing the adequacy of technological maturity. The TRA scores the current readiness level of a selected technology or system, using defined Technology Readiness Levels (see below, and Annex A). The TRA essentially "draws a line in the sand" on the day of the evaluation to allow making an assessment of technology readiness for critical technologies.

It is through a Technology Readiness Assessment that the Alliance can determine whether a technology is sufficiently advanced to allow its effective evaluation for use in the NATO multi-national medical environment. If the determination of a TRA were that the system does not meet pre-defined Technology Readiness Level scores, then further testing in the NATO T&E program would not be indicated at that time.

2.4 TECHNOLOGY READINESS LEVELS (TRLS)

The concept of Technology Readiness Levels is simply that of a uni-dimensional scale used to provide a measure of technological maturity at a given point in time. Its use can provide a repeatable system for measuring a technology's maturity by identifying a "Snap shot" of technological maturity at the time of

[9] Technology Readiness Assessment (TRA) Deskbook.

evaluation. The use of TRLs is therefore fundamental to any evaluation of new technology in our environment. A TRL value indicates only what has already been accomplished in the development of a technology – it does not indicate that the technology is right for the job or that application of the technology will result in successful development of the system. Neither does it address the questions of "Can it be used, and does it do what it is expected to?" or "How does it affect doctrine?" – Those questions must be answered by an operational test and evaluation system.

Technology Readiness Levels were originally developed by The United States' National Aeronautics and Space Administration (NASA) in the late 1980s (Table 2-1). The original definitions only included seven levels, which were clearly defined so as to apply to the NASA mission. These seven levels were later expanded to nine levels, as experience showed the deficiencies in the use of only the original seven levels in an operational setting.

Table 2-1: Original NASA TRL Definitions[10]

Level	Description
Level 1	Basic Principles Observed and Reported
Level 2	Potential Application Validated
Level 3	Proof of Concept Demonstrated, Analytically and/or Experimentally
Level 4	Component and/or Breadboard Laboratory Validated
Level 5	Component and/or Breadboard Validated in Simulated or Real-Space Environment
Level 6	System Adequacy Validated in Simulated Environment
Level 7	System Adequacy Validated in Space

Though NASA successfully used these TRLs, other agencies which looked at the system determined that for ease of use and uniformity of application, the definitions characterizing each level needed to be more detailed and comprehensive. The United States Air Force adopted the use of Technology Readiness Levels in the 1990s, but they did not become widely used in the USAF until 1995, when John C. Mankins of NASA proposed much more detailed descriptions for each TRL[11]. In 1999, the United States General Accounting Office (GAO) produced an influential report[12] which examined the differences in technology transition between the United States DoD and private industry. It concluded that the DoD took greater risks and attempted to utilize emerging technologies at lesser degrees of maturity than did private industry. The GAO concluded that use of immature technology increased overall program risk, and recommended that the entire DoD adopt the use of NASA's TRLs as a means of assessing technology maturity prior to transition. Finally, in 2001, the Deputy Under Secretary of Defense for Science and Technology issued a memorandum which endorsed the use of TRLs in all new major programs, which was subsequently incorporated into DoD

[10] Sadinst, et al., "NASA Technology Push Towards Future Space Mission Systems".

[11] Mankins, J.C., "Technology Readiness Levels: A White Paper".

[12] GAO/NSIAD-99-162.

acquisition Guidance[13,14]. The following TRLs are now in use in all non-medical acquisition and materiel development programs within the United States Department of Defense (DoD) (Table 2-2).

Table 2-2: U.S. DoD-Defined TRLs[15]

Level	Description/Supporting Information
1) Basic principles observed and reported	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties. Published research that identifies the principles that underlie this technology. References to who, where, when.
2) Technology concept and/or application formulated	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies. Publications or other references that outline the application being considered and that provide analysis to support the concept.
3) Analytical and experimental critical function and/or characteristic proof of concept	Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative. Results of laboratory tests performed to measure parameters of interest and comparison to analytical predictions for critical sub-systems. References to who, where, and when these tests and comparisons were performed.
4) Component and/or breadboard validation in [a] laboratory environment	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" hardware in the laboratory. System concepts that have been considered and results from testing laboratory-scale breadboard(s). References to who did this work and when. Provide an estimate of how breadboard hardware and test results differ from the expected system goals.

[13] Defense Acquisition University, Interim Defense Acquisition Guidebook.

[14] Deputy Under Secretary of Defense for Science and Technology (DUSD (S&T)), Technology Readiness Assessment (TRA) Deskbook.

[15] Defense Acquisition University, Interim Defense Acquisition Guidebook.

Level	Description/Supporting Information
5) Component and/or breadboard validation in [a] relevant environment	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment. Examples include “high-fidelity” laboratory integration of components. Results from testing a laboratory breadboard system that are integrated with other supporting elements in a simulated operational environment. How does the “relevant environment” differ from the expected operational environment? How do the test results compare with expectations? What problems, if any, were encountered? Was the breadboard system refined to match the expected system goals more nearly?
6) System/sub-system model or prototype demonstration in a relevant environment	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology’s demonstrated readiness. Examples include testing a prototype in a high fidelity laboratory environment or in [a] simulated operational environment. Results from laboratory testing of a prototype system that is near the desired configuration in terms of performance, weight, and volume. How did the test environment differ from the operational environment? Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?
7) System prototype demonstration in an operational environment	Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle, or space. Examples include testing the prototype in a test bed aircraft. Results from testing a prototype system in an operational environment. Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?
8) Actual system completed and qualified through test and demonstration	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications. Results of testing the system in its final configuration under the expected range of environmental conditions in which it will be expected to operate. Assessment of whether it will meet its operational requirements.

Level	Description/Supporting Information
8) Actual system completed and qualified through test and demonstration (cont'd)	What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before finalizing the design?
9) Actual system proven through successful mission operations	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions. Operational test and evaluation reports.

Since acceptance by the U.S. DoD, the concept of TRLs has been accepted by many other program managers, agencies, corporations, and nations. The concept of the use of TRLs as a tool to describe the maturity of technologies being considered for new systems or for fielding is now widely accepted in materiel development and acquisitions programs worldwide. NATO has never formally accepted the concept of TRLs, though the NATO Undersea Research Center (NURC) has developed a set of TRLs which they have recommended be adopted by the Allied Command Transformation's (ACT) Technology Advisory Board (TAB)[16]. These proposed TRL definitions go beyond those currently adopted by the U.S. DoD, and are felt by the NURC to be more compatible with NATO needs. Unlike the NASA originals, each readiness level is defined in general terms according to the state of technological development, and is additionally described in detail to assist the user in determining into which category a given technology may fall (Table 2-3). (It has been reported to us that these may have already been approved in concept by RTO, but we can find no evidence of this in RTO documentation. In any case, they are not quite suitable for biomedical usage as presented.)

Table 2-3: NURC-Recommended NATO TRLs[17]

NATO Technology Readiness Level	Description
0) Basic research with future military capability in mind	Systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and/or observable facts with only a general notion of military applications or military products in mind. Many levels of scientific activity are included here but share the attribute that the technology readiness is not yet achieved.
1) Basic principles observed and reported in context of a military capability shortfall	Lowest level of technology readiness. Scientific research begins to be evaluated for military applications. Examples of R&T outputs might include paper studies of a technology's basic properties and potential for specific utility.
2) Technology concept and/or application formulated	Invention begins. Once basic principles are observed, practical applications can be postulated. The application is speculative and there is no proof or detailed analysis to support the assumptions. Example R&T outputs are still mostly paper studies.

[16] NURC, NATO Technology Readiness Levels.

[17] Ibid.

NATO Technology Readiness Level	Description
3) Analytical and experimental critical function and/or characteristic proof of concept	Analytical studies and laboratory/field studies to physically validate analytical predictions of separate elements of the technology are undertaken. Example R&T outputs include software or hardware components that are not yet integrated or representative of final capability or system.
4) Component and/or breadboard validation in laboratory/field (e.g., ocean) environment	Basic technology components are integrated. This is relatively low fidelity compared to the eventual system. Examples of R&T results include integration and testing of ad hoc hardware in a laboratory/ field setting. Often the last stage for R&T (funded) activity.
5) Component and/or breadboard validation in a relevant (operating) environment	Fidelity of sub-system representation increases significantly. The basic technological components are integrated with realistic supporting elements so that the technology can be tested in a simulated operational environment. Examples include high fidelity laboratory/field integration of components. Rarely an R&T (funded) activity if it is a hardware system of any magnitude or system complexity.
6) System/sub-system model or prototype demonstration in a realistic (operating) environment or context	Representative model or prototype system, which is well beyond the representation tested for TRL 5, is tested in a more realistic operational environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high fidelity laboratory/field environment or in simulated operational environment. Rarely an R&T (funded) activity if it is a hardware system of any magnitude or of significant system complexity.
7) System prototype demonstration in an operational environment or context (e.g., exercise)	Prototype near or at planned operational system level. Represents a major step up from TRL 6, requiring the demonstration of an actual system prototype in an operational environment, such as in a relevant platform or in a system-of-systems. Information to allow supportability assessments is obtained. Examples include extensive testing of a prototype in a test bed vehicle or use in a military exercise. Not R&T funded although R&T experts may well be involved.
8) Actual system completed and qualified through test and demonstration	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of Demonstration. Examples include test and evaluation of the system in its intended weapon system to determine if it meets design specifications, including those relating to supportability. Not R&T funded although R&T experts may well be involved.
9) Actual system operationally proven through successful mission operations	Application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation and reliability trials. Examples include using the final system under operational mission conditions.

Normally, the definitions of and references to TRLs are almost always in engineering terms, but the TRL concept is applicable to any technology. Medically-related items require TRL definitions and descriptions that are appropriate to the technologies upon which they are based, and that account for the specialized statutes and regulations which govern their development and use. Neither the NASA, the DoD, nor the NURC TRL definitions are directly suitable for use in evaluating the status of biomedical technologies. In many ways, biomedical technologies are more complex than the vast majority of engineering and design technologies involved in even space flight. There are several categories of biomedical technologies which each demand modified TRLs to appropriately assess them. Further, most biomedical technologies are subject to stringent regulatory controls (e.g., the U.S. Food and Drug Administration (FDA) or the European Union's European Medicines Agency (EMEA)), which must be applied at various levels of development. Thus, taking these regulatory requirements into account is also a requirement when assessing whether a biomedical product (whether drugs, vaccines, or equipment) is ready for NATO use. In searching for a TRL set which is suitable for use in the biomedical arena, the most useful one we have found is that developed for the U.S. Army Medical Research and Materiel Command[18]. However, this particular set of TRLs seems too U.S.-centric for NATO use as originally prepared. Accordingly, the RTG has modified this set of biomedical TRLs for NATO use by referring to generic national or EU approval bodies and procedures rather than the U.S. FDA and U.S.-specific development processes, etc. There are five categories of biomedical products, which each have differing technological and developmental requirements. Thus, the TRLs for each are a bit different. In much medical technology, software is considered an integral part of the system or sub-system in which it operates. Therefore, demonstration of a technology at the sub-system or system level must include demonstration of the associated software. Although at the present time we believe that the potential for NATO as an alliance becoming involved in drug or vaccine development is remote, we cannot eliminate it as a future possibility. Therefore, although the primary purpose of our proposed T&E system is to analyze the other three categories of biomedical developments, we have also provided TRLs for both drug and vaccine development in the interests of completeness, either for Alliance use or for use by nations which wish to make use of this concept. Additionally, we have provided clear descriptions of those evaluation criteria which can be used to define at which TRL a technology is currently found. It should be noted that activities described as occurring between successive TRL Decision Criteria are intended to exemplify the kinds of activities that routinely take place when maturation is sequential and stepwise – these examples are neither mandatory nor all inclusive. The lower a critical technology's TRL when transitioning from technology development to product development, the greater the risks of failure. For medical technologies, risk reduction is not linear across TRLs. The rate of risk reduction remains very low until very late in development. We propose that the biomedical TRL matrix shown in Annex A be formally adopted by NATO, and used as the basis for screening of biomedical technology before entry into the proposed NATO T&E system proposed below. Further, we recommend that no item or technology be accepted for testing in the below-recommended T&E Scheme unless it is adjudged to be at least at TRL 6.

[18] Sciences Applications International Corporation. "Biomedical Technology Reference Levels (TRLs)".

Chapter 3 – MEDICAL EQUIPMENT TESTING CATEGORIES AND METHODOLOGY

There are many different aspects of medical equipment testing, each with their own techniques and requirements. In deciding to undertake a medical Test and Evaluation program, decisions must be made as to what type of testing is desired or needed prior to developing the test plan.

3.1 FUNCTIONAL TESTING

3.1.1 Functional Tests

Functional tests focus mainly on matching expected system behavior against an agreed functional specification (inputs, system behavior and expected outputs). Experimental tests or observational study outcomes can be derived by box-ticking lists of a set of criteria, user group interviewing or observation of end users using the system and logging of system responses. The test specification (criteria, measured variables, use cases and testing methodology) must be agreed during the system definition phase and/or negotiated with the client as project deliverables (success criteria). Chapter 4 should be consulted for details of developing such specifications.

3.1.2 Hardware and Software Testing

Hardware and software testing involve different applications under the same testing rationale. For example for stress testing of software components, multiple protocols are applied under heavy load and usage patterns to observe system behavior and results, while hardware testing may include physical parameters such as high voltage, frequencies, processor loads, over- and under-clocking, heat, cold, dampness, etc. A large number of regulations and procedures exists for domain-specific tests (e.g., FCC, TÜV, CE, EU directives), and these policies should be consulted prior to developing a test process.

3.1.3 Non-Functional Testing of Operation of the Equipment

3.1.3.1 Performance Testing

Performance testing includes an assessment and analysis of response time, listed output measures, and scalability. Typically, an experimental set-up is used for the assessment of quantitative measures (these are defined during the system development phase, particularly in a test plan document).

3.1.3.2 Reliability Testing

Reliability testing is performed with a test set-up with varying expected usage patterns, which is used for the collection of performance, stability and effectiveness data. The focus can be on detection of faults for later removal (defect testing) or the focus can be on reliability evaluation for gaining confidence in system performance.

3.1.3.3 Stress Testing

Stress testing can be carried out by means of an experimental study where system behavior is assessed by going beyond normal operational capacity or to a breaking point. Prospective aspects of studies involve

automated script based testing (e.g., burn-in test) and by tests with several users trying out various usage scenarios with the intent of faulting the system. With a stable delivered system, a retrospective analysis of logs of real usage data can be used.

3.1.3.4 Workload Testing

Workload testing involves analysis of system behavior under normal operation using retrospective analysis of logs of real usage data. Also, automated burn-in testing can be deployed.

3.1.3.5 Data Integrity Testing

Data integrity testing involves the experimental testing of data integrity over time as testing under various system conditions is conducted. Measures of completeness and accuracy of the stored data, data in transit and during processing are collected and analyzed.

3.1.3.6 Error Handling Testing

Error handling testing evaluates operator or user performed rules or use case based testing (domain specific standards or rules predefined during development and resulting rules-scenarios from stress testing) of system performance in internal and external error events. Data covering recovery behaviors, information about status and user guidance variables are collected and analyzed.

3.1.3.7 Recovery Testing

Recovery testing involves experimental, operator-led study of system ability to recover from crashes, hardware failures, etc. In addition log-based retrospective, observational studies are conducted after system delivery.

3.1.3.8 Software Regression Testing

Software regression testing involves tests of system functioning and reliability after bug fixing, upgrading, parameter changes, etc. Either focused tests of selected affected features (use cases) or full-scale post-tests for reliability, performance and stress are performed.

3.1.3.9 Compatibility Testing

Compatibility testing requires the testing of standards compliance, interoperability, connectivity, interfacing, attached or co-used hardware, backwards compatibility, etc. – i.e., compatibility within the working/functional environment.

3.1.3.10 Maintenance Testing

Maintenance testing involves the analysis of typical use-related problem identification (system responses, feedback, status reports), cost and performance data for preventive and corrective maintenance, post-repair reliability control, and quality control.

3.1.3.11 Security Testing

Security testing utilizes experimental tests assessing the system's ability to contain data integrity, data authentication, user authorization, confidentiality, later non-repudiation of user or illicit actions and

system's ability to uphold functionality. Tests involve software based and physical break-ins, hacking, known software bug exploitations.

3.1.3.12 Usability Testing

Usability testing involves various tests measuring the system's capacity to meet its intended purpose, highlighting ease of use, efficiency of usage, accuracy of usage, ease of learning and recalling, satisfying pleasing and emotional values of end users, etc. The goals of usability testing fall either into the creation of records of usability benchmarks for future releases or for minimizing the cost of service and support; minimizing risk of adverse behaviour, etc. Tested and monitored variables are selected according to above goals. Furthermore, usability testing can be seen of having following distinctions:

- **Exploratory tests** engage focus groups to evaluate the effectiveness of design concepts. Observer lead user querying and monitoring tests are performed.
- **Assessment tests** evaluate usability of lower-level operations and aspects the system. Quantitative measures of screens, buttons, or clicks performed without an observer's intervention are collected and analyzed.
- **Validation tests** compare usability against predetermined usability benchmarks (internal company or external standards. Heuristics checklist, quantitative data from user behavior performing given tasks, focus on data collection, but also situations of sub-standard performance are identified.
- **Comparison tests** are used in conjunction with other usability tests to compare two or more alternative designs with current system. Alternatives can be prototypes or existing products.
- **Accessibility testing** are tests assessing usability criteria in varying environmental conditions (light and dark lighting conditions, in- and out-doors, noisy environment, during movement, etc.), tests assessing system usability for people with special needs, etc.
- **User help testing** is an experimental study of user support functionality – an observational study of users needing help, their actions accessing, using and understanding support system, and results in a user satisfaction assessment.
- **Installation testing** is the review of tasks of system set-up by the user in the user's environment. It provides measures regarding reliability, ease of use, resource and knowledge requirements, etc., which are collected and analyzed.
- **Documentation testing** involves judgment of the effectiveness and usability of supporting documentation. Document comparison against others of the same type is one possible tool. Examination of typographical errors and reconsideration error of meaning using independent readers, focus group testing of knowledge after reading the document, and focus group testing of finding relevant information are other modalities used in this context.

Chapter 4 – PROPOSED NATO MEDICAL TEST AND EVALUATION MANAGEMENT

4.1 PURPOSE

This chapter contains information, guidance, and best practices pertaining to systematic test and evaluation (T&E) and related subjects. Our goal is to propose an operational test and evaluation system to be used in conjunction with future NATO medical technologies evaluation which can be implemented by NATO bodies and programs as recommended above in Chapter 2. We are not discussing routine procurement acceptance testing, as is routinely done by procurement organizations, though for completeness that is discussed briefly in Annex B. This test system is designed to evaluate mature technologies under consideration for inclusion in NATO medical systems – i.e., in the early stages of the acquisition process. Operational testing determines "if things (e.g., devices, systems) work and have operational benefits". **It is not the intent nor is it within the scope of this document to recommend or to build a new T&E structure.** Our goal is to provide guidance and support to those who may have to carry out NATO T&E under the direction of ACT, or whatever other NATO agency is formally tasked to carry out this mission, hereinafter referred to as the NATO Test Organization (NTO).

4.2 OTHER MANDATORY DOCUMENTS

This chapter should be used in conjunction with policies and best practices from other NATO groups and international test organizations. Advanced Concept Technical Demonstrations (ACTD) which show "how things work", rather than "if things work" for example, share many test principles with operational testing and so NATO demonstration policy and doctrine should be reviewed[1], along with Chapter 5 of this report (which discusses Medical Technology Demonstrations (MTD)), in preparation for NATO operational T&E. Readers might also wish to familiarize themselves with the NATO and member nation documents in the reference list associated with this report.

4.3 HOW TO USE THIS CHAPTER

This chapter is set up to be utilized as a guide regardless of whether NATO creates a specific T&E organization at some point in time, assigns these responsibilities to an existing NATO organization [e.g., Allied Command Transformation (ACT) or the NATO Maintenance and Supply Agency (NAMSA)], or if a member nation test organization performs the testing on behalf of the Alliance. At the current time, it appears as though NATO is primarily interested in field demonstrations so operational testing of this nature is emphasized in this technical report.

4.4 THE UNDENIABLE NEED FOR T&E

T&E must demonstrate capabilities today that will be needed tomorrow throughout the entire spectrum of NATO missions from humanitarian support to a full Article 5 operation. When a capability is called for in order to provide combat medical support, the need is immediate and there is no time to consider whether or not the system will operate as designed or whether it can be effectively used by all potential users in the context of an

[1] For example, NATO Guidance for Experimentation Planning (NAGEP) Revision 2.

operational scenario. NATO / Partnership for Peace (PfP) military personnel and their leaders need assurance that when they risk their lives, the medical systems provided to them will do the job for which they were designed.

4.4.1 Desired Outcomes

The desired outcomes of T&E programs include: product maturity evaluation (discussed more fully in Chapter 2 and Annex A), management of risks (Chapter 6), identification of deficiencies (Chapter 7), and assurance that systems are operationally effective and suitable (Chapters 4 and 5). The NATO T&E community should conduct integrated T&E on a continuum in collaboration with ongoing requirements development and during the later phases of the acquisition process.

4.4.2 Deficiency Evaluation

Credible T&E data about the development and continued sustainment of medical systems is needed in order to ensure operational readiness in the multi-national operational environment. If equipment deficiencies are documented, medical planners can plan around these deficiencies and medical logisticians can attempt to remedy the identified deficiencies.

4.5 PROPOSED NATO T&E ORGANIZATIONAL STRUCTURE

4.5.1 Organization in Charge of Test and Evaluation

At the time of this publication, the authors do not know what NATO organization will be placed in charge of medical T&E programs. Likely candidates for this task are the Allied Command Transformation (ACT) or the NATO Maintenance and Supply Agency (NAMSA), and we believe that ACT would be the most appropriate agency to carry out this task, as recommended above. For the purposes of this document, the organization in charge of medical equipment T&E will be referred to as the NATO Test Organization (NTO). **Note that in the use of this terminology we do NOT envision the creation of a stand-alone formal T&E organization, but simply recognizes that some organization must be formally in charge of any such program.** The tasks identified below must be carried out, no matter which organization is assigned the responsibility, and failure to have them managed/supervised by a single organization with knowledge and responsibility for the functions of such a program is a sure route to lack of success.

4.5.2 NATO Test Organization (NTO) T&E Responsibilities

The NTO should be assigned the following responsibilities related to the fielding of medical technologies: determine the need for T&E, create the requirements for T&E, create the test plan, assign/coordinate for some functional body to carry out the actual T&E process, develop the assessment metrics, supervise the T&E, and review and analyze the results of the test program. Either the NTO or some other body tasked to do so must undertake an oversight role of the process.

4.5.3 Oversight Functions

Oversight functions include requirements that the NTO:

- Provide early involvement in drafting the T&E strategy.

- Supervise testing and evaluate the impact of deploying a device or system on the operational mission. The NATO oversight team should look at the system being tested with all interoperability and supportability considerations taken into account; then ensure that systems are operationally effective and suitable before these systems go to fielding.
- Ensure that T&E is adequately completed prior to deployment of new advanced medical technology, and that the tests were properly executed according to NATO guidance.

4.5.4 NATO T&E Oversight

NTO criteria to be considered in making the determination as to whether or not a piece of equipment or a medical system should be tested in accordance with this document should include:

- TRL level (see Annex A) of the proposed equipment to be tested.
- Stage of development or production of the item/device/system being evaluated.
- Whether or not other developmental and/or operational testing, the results of which can be utilized, has been done in Alliance or PfP nations.
- Whether or not there is inter-nation compatibility.
- Whether or not there is NATO/PfP member nation interest in the technology.
- Whether or not the technology meets regulatory requirements (refer to Annex B).
- Relationship with other medical systems as part of a system-of-systems.
- Technical complexity of system (e.g., Medical Device Classification, ref. Section 6.1).

4.6 T&E SUPPORT TO THE REQUIREMENTS PROCESS

4.6.1 Operational Requirements Development and Review

In general terms, when NATO is considering acquisition or fielding of new medical technology on an Alliance basis, Allied Command Operations (ACO) and/or ACT should set the requirements, while the NTO or another organization tasked by the NTO should do the testing. Testing organizations utilized for NATO testing should be involved in the NATO requirements creation process if possible. A suggested NATO requirements development group would include a group of potential users and subject matter experts (SMEs). Before developing test strategies and plans, all testers should thoroughly understand the underpinnings of their test programs, namely the operational capability requirements from which that testing will be derived.

4.6.2 Requirements Development

Testable requirements development must utilize representatives from developmental and operational test organizations (those who will actually carry out the testing) as well as doctrinal experts and potential end-users (those who will have to use the equipment) in order to achieve optimal representation. The test planners will determine who will need to participate, and at what level their involvement will be in the requirements development process.

4.6.3 Review of Requirements Policies Impacting T&E

4.6.3.1 Support

The requirements strategy must reflect the required capabilities outlined in applicable NATO concepts of operations, NATO policy and doctrine, and capability-based planning documents. Applicable medical device classification to include member nation regulations should be considered in requirements development. Regulatory authorities recognize different classes of medical devices, based on their design complexity, their use characteristics, and their potential for harm if misused. Each country or region defines these categories in different ways. The authorities also recognize that some devices are provided in combination with drugs, and regulation of these combination products takes this factor into consideration (ref. Section 6.1). Each strategy must be tailored to address strategy elements such as: member nation interoperability/implications, funding, test schedules, testing mechanisms, supportability, training, analysis, human systems integration, potential challenges and constraints, etc. Following the development of the requirements strategy, and prior to documenting the needed capabilities in an operational requirements document, the sponsor presents the requirements strategy to the NATO leadership for approval.

4.6.3.2 Requirements Development

The NATO leadership should assign a requirement development team for the test process consisting of Subject Matter Experts (SMEs) from the member nations or from other appropriate NATO organizations. It is important that the capabilities described in the test requirement documents be as clear and detailed as possible. The focus is on understanding the required capability as well as making sure the requirements are testable. The reader should refer to the references and to Annex C for guidance concerning medical technology requirements development.

4.6.4 The Integrated Testing Process

The integrated testing process is a well-proven structured system for identifying testable requirements, developing a concept by which those requirements will be tested, analyzing the results, and finally reporting the results so that appropriate actions may be taken by NATO. It provides a road map which, if adequately developed in detail, will make the actual carrying out of the test or project much easier than if it is not followed.

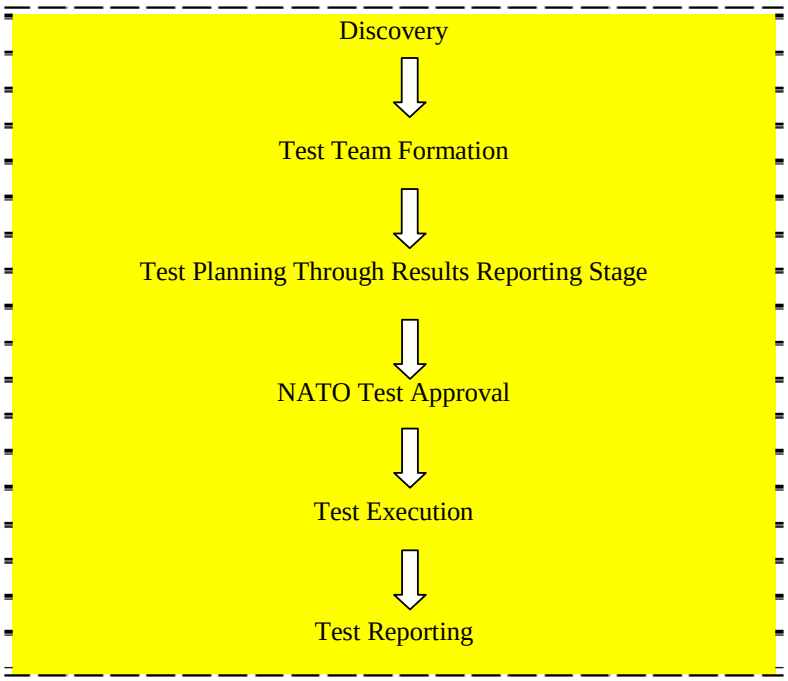

Figure 4-1: Outline of the Integrated T&E Process.

4.6.4.1 "Discovery"

"Discovery" is the process by which NATO leadership becomes aware of the need for utilization of the Test and Evaluation process. This information may arise from review of findings by the NATO Joint Analysis and Lessons Learned Centre (JALLC), from decisions of the COMEDS Plenary, from the Strategic Commands, from work carried out by the Research and Technology Organization (RTO), or from any of a myriad of other NATO Expert Panels, Expert Teams, and Work Groups.

4.6.4.2 Test Team Formation

After discovery of a test and evaluation requirement, the first challenge in the NATO T&E process is to identify the end-user community and appropriate T&E participants. A test team is established to facilitate formal early tester involvement and carry out all T&E planning, execution, and reporting for the program.

4.6.4.3 Test Planning Through Results Reporting

One of the primary functions of the test team is to integrate test planning from initial test design and concepts through to a Test and Evaluation Master Plan (TEMP) approved by the NATO leadership or by the NTO for execution; then they must carry out the test and report the results so that decisions may be made by the NATO leadership regarding the object of the tests.

4.6.5 Operational Test Development

Just as is the overall integrated testing process, the mechanism for development of the full operational test as part of that process is well-defined and well-proven to be effective. It has several stages, each of which

necessarily leads to the next, and finally to a reportable result. Though the contents of each of these steps may be modified to reflect the realities of NATO posture and equipment to be tested, a positive "check-off" should be made at each stage of the planning process to ensure that no important steps are missed.

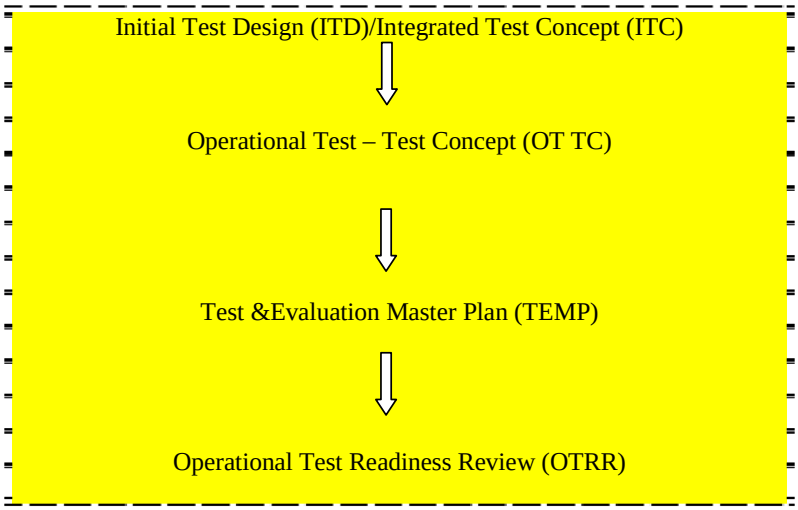

Figure 4-2: Basic Outline of the Test Development Process.

4.6.5.1 Initial Test Design (ITD) / Integrated Test Concept (ITC)

The ITD starts the iterative process of test concept and test plan development that culminates in executable test plans. The ITD process culminates in an Integrated Test Concept (ITC) that includes an initial description of test scenarios, test locations, exercises, T&E methodologies, operational impact assessments and issues, and projections for future increments. The test plan fleshes out and documents the details that are known at the time of pre-test planning in order to build a solid basis for a test approach and to communicate that approach to others. This is accomplished by identifying the battle space conditions and testing constraints, thereby leading to a set of test events. Further discussion leads to a basis of estimate and the identification of resources (test articles, personnel, etc.), determination of execution methodologies (field test, modelling/simulation, etc.), identification of test capability requirements and shortfalls, and refinement of the operational test activities and schedule.

4.6.5.2 Operational Test – Test Concept (OT TC)

The OT TC is a detailed, fleshed-out update of the approved initial test design, of which an outline is found at Annex D. It includes:

- Review of requirement documents to ensure that operational requirements will be met (A proposed method for reviewing Capabilities-based requirements documents is found at Annex C);
- Refinement of test methodologies;
- Identification of evaluation criteria;
- Determination of the rating methodology for operational effectiveness and suitability;
- Refinement of the sample size;

- Determination of realistic test scenarios;
- Development of a plan for the use of exercises and test capabilities needed to support operational test execution; and
- Identification of testing events that are required to support operational test conclusions.

4.6.5.3 Test and Evaluation Master Plan (TEMP)

The TEMP will identify data and resource requirements to support the assessment/evaluation. It will list Measures of Performance (MOP) which will be analyzed, as well as describe test limitations, safety and security issues, specific test events, scenarios, schedule, measures, data collection (who, what, when, where, why and how), reduction, and analysis. It will show linkages between data to be collected, information to be obtained, and conclusions needed. The NTO should review and approve the TEMP prior to the start of any actual testing.

4.6.5.4 Operational Test Readiness Review (OTRR)

The OTRR is a means for the NTO operational test leadership to review readiness for dedicated operational testing. NATO may utilize member nation test experts to provide this service. The OTRR will address operational test posture and review actions of contributing agencies in preparation for test start. The review includes the status of operational test readiness certification (see below), test plan changes, test team status (staffing and training), test capability status, and general confidence that the system is ready to begin operational testing. The status of time, cost, resources, and scope baselines should be discussed. Any OTRR should satisfy senior decision makers that:

- The system is ready for the test;
- Pre-test analysis includes the assurance that test outcomes will address objectives;
- Test resources and personnel are completely prepared for the test;
- Known anomalies (e.g., fewer than the standard number of end-user participants) have not increased the risks associated with executing the test;
- All reasonable efforts have been made to minimize risk; and that
- Test results will provide the appropriate inputs for decision-making regarding the tested system.

4.6.6 Test Team Concepts, Tools and Techniques

Special Note: The functions implied in this section do not necessarily require separate teams, groups, or committees but are discussed separately to identify discrete functions which must be accomplished. The functions can be incorporated into presently defined NATO components (e.g., ACT, NAMSA, NTO, or Expert Groups).

4.6.6.1 Data Management

All testers will establish rigorous data control and accountability procedures. All T&E team members share in the responsibility for acquiring, monitoring, controlling, and assuring the quality and security of T&E data supporting the test.

4.6.6.2 Timely Data Analysis

The quality of the test results is largely determined by the quality of the test data. First hand observation of test conditions and execution is the best means of ensuring data are objective and ultimately useful. Test teams must constantly assess if sufficiently accurate data is being collected and if the appropriate analytical techniques are supporting the test objectives as the test progresses. Data analysis should be done concurrently with test execution if possible.

4.6.6.3 Timely Release of Data

All testers will release validated test data and factual information as early as practical to the NTO or to contractors who directly support NATO. This data may be preliminary and if so should be clearly identified as such. Some types of data and test information that are evaluative in nature, such as scoring of failures or opinion surveys, can be withheld until the evaluation and final report are complete.

4.6.6.4 Recording Data Origins

The origins of all T&E data must be accurately identified, validated, and recorded. Testers may use data from a wide variety of sources, such as system or support contractors, other member nation and NATO agencies, exercises and experiments, and any prior operational testing. The goal is to obtain sufficient amounts of useable and credible data to enhance confidence in the results and thus enable better support program decisions.

4.6.6.5 Certification Readiness for Operational Testing

The NTO should formally certify that systems are ready to enter the dedicated phase of operational testing prior to the actual start of a test program. Coordination between NATO testers and the NTO is necessary to identify and resolve any concerns about system maturity, verification of test assets, resources, facilities and equipment required for the test.

4.6.7 Contractor Involvement in T&E

Many professional test organizations place strict limits on contractor involvement in T&E. Contractors may be involved in the test process, but their responsibilities must be clearly delineated in the test plan. Operational testers must carefully distinguish between two fundamentally different types of contractors: prime or system contractors who build the system, and support contractors who support NATO in carrying out its functions. The first group may have inherent biases regarding the outcome of the testing, and may have vested interests in the outcome – their companies may stand to profit if the tested equipment is procured for NATO use. The second group may be considered essentially as NATO employees for the purposes of this testing, and should be presumed to be neutral as to the outcome of the T&E process.

4.6.7.1 System Contractors

Operational testers must strictly avoid situations in which system contractors could influence or reduce the credibility of T&E results, or could compromise the realistic and unbiased accomplishment of T&E scenarios. Operational testers must ensure the quality and integrity of any system contractor data used for the integrated portions of dedicated T&E. The data must be accurate, objective, reliable, and available for independent evaluation.

4.6.7.2 Support Contractors

The limitations on support contractor involvement in OT&E are distinctly different than those for system contractors. Generally speaking, system contractors will not be involved in the establishment of criteria for data collection, performance assessment, or evaluation activities for the T&E process. This limitation does not apply to a support contractor which has participated in such development, production, or testing solely in testing or test support on behalf of NATO. For example, a support contractor working for NATO on the same program may also be involved in the T&E. Support contractors may be used to collect and manage data in support of T&E evaluations.

4.6.7.3 Areas in Which System Contractors May Support T&E

System contractor support in the T&E process may be beneficial in providing logistical support, test failure analyses, and software and instrumentation support which would increase the value of T&E data generated, while maintaining the integrity of test results:

- They may be involved in conducting and reporting analyses of test failures to assist in isolating causes of failure, but excluding participation in data scoring and assessment conferences.
- Their activities may legitimately include providing and operating system-unique test equipment, test beds, and test facilities which may include software, software support packages, instrumentation and instrumentation support.
- They may assist by providing logistical support and training as required in the event that such services have not yet been developed and are not available from NATO or any national sources.
- Prime Contractors may be involved in the T&E process by providing data generated prior to the conduct of the T&E, if deemed appropriate and validated by the NTO in order to ensure that critical issues are sufficiently and adequately addressed.

4.6.8 NATO Member Nation-Specific Operational Testing

When NATO member nation-specific test organizations can uniquely meet NATO's testing requirements, the NTO can request that that test organization provide the operational testing. If individual nations perform the testing on behalf of NATO, they must abide by the same requirements as would NATO itself in carrying out the testing, as expressed in this document.

4.6.9 NATO Test Organization Support

Per the NATO Experimentation Programme of Work (EPOW), member nation test responsibilities include support of NATO-conducted operational tests. When the NTO requires support from a member nation test organization, the level of support, specific dates for support, and a list of needed resources should accompany the support request and will be agreed upon, in writing, between the NTO and the member nations' test organizations. If member nations are providing testing services for NATO, NATO needs to approve the test plan. National processes must essentially cover the NATO requirements, even though the established national processes may have many more required steps and details. The elements of the NATO T&E strategy will be clearly delineated and will be met. Test reports will include at a minimum that data required of a NATO-performed test.

4.7 TEST AND EVALUATION RESULT REPORTING

A major function of testing is the early identification, documentation, reporting, and tracking of system deficiencies and enhancements. NTO has overall responsibility for establishing and administering a deficiency reporting system for the program, which will report in detail all goals or activities in which the equipment failed to meet the test requirements. NTO will establish procedures for submitting, screening, prioritizing, and tracking Deficiency Reports (DR) from all sources. An example of an Operational Test Final Report outline is found at Annex E.

4.7.1 Results from Operational Testing

Specific procedures outlined in the TEMP will be used to create the DR, and DRs will be submitted promptly after conclusion of the test. There are two categories of DRs which are described in the Reference section of this report. NTO will develop a set of reports and official recommendations as related to test outcomes. All Recommendations arising from the test will be reported to ACO, the Committee of the Chiefs of the Military Services in NATO (COMEDS) and the NATO Joint Analysis and Lessons Learned Center (JALLC). Testers will supply all available data to assist the NTO in analyzing and fixing problems identified and reported in the DR.

Chapter 5 – MEDICAL TECHNOLOGY DEMONSTRATIONS (MTDs)

5.1 INTRODUCTION

One mechanism for carrying out a proposed T&E procedure for advanced medical technology in an effort to determine how this technology will fit into (or affect) NATO medical doctrine is the Medical Technology Demonstration (MTD). MTDs demonstrate the potential exploitation of mature advanced medical technologies to solve important military problems. The global proliferation of advanced medical technologies and the existence of potential adversaries with relatively easy access to these technologies have increased the need to rapidly transition technology from the developer to the user. MTDs are structured to address the needs of the warfighter; to provide needed medical capabilities, address identified deficiencies, and reduce costs or manpower requirements of medical support options. Each MTD is aimed at one or more warfighting objectives and should be reviewed by the COMEDS and by ACO prior to being carried out. An MTD can be carried out as part of a larger formal T&E process, or can be done in a focussed and more limited manner as a stand-alone effort.

5.2 OBJECTIVES OF MTDs

The objectives of an MTD are:

- To conduct meaningful demonstrations of the medical capability;
- To develop and test concepts of medical operations to optimize military effectiveness; and
- To prepare to transition the medical capability into acquisition without loss of momentum, if warranted.

5.2.1 Conduct Meaningful Demonstrations of the Medical Capability

The demonstrations are sized and structured to provide a clear evaluation of the effects of the equipment being tested on military medical capability. The user defines the measures of effectiveness and measures of performance that allow effectiveness and suitability to be characterized. Data collection is tailored accordingly. The quantity of systems in the MTD must be sufficient to provide a valid assessment of the medical capability, or simulations are used to expand the battlespace and forces involved in the exercise. The user provides, or at least approves, the planned operational exercises which typically include red as well as blue forces (Alliance and Opposing Forces). As a means of demonstrating the use of mature medical technology to address military requirements, each MTD must:

- Evaluate the military utility and the ability of proposed solutions to meet critical military needs;
- Develop a robust concept of operations; and
- Refine requirements.

5.2.2 Develop and Test Concepts of Operations

MTDs are frequently based on advanced medical technologies which may permit – or even demand – new concepts of operation, tactics, and doctrine in order to realize their maximum potential. The MTD provides a means to develop, refine, and optimize these warfighting concepts to achieve maximum utility and effectiveness.

5.2.3 Prepare to Transition into Acquisition

A key goal of MTDs is to move into the appropriate phase of formal acquisition without loss of momentum, assuming the user provides a positive evaluation of the medical capability. Each MTD should have a clear acquisition goal covering both the MTD and post MTD phases. They also must have a supportability concept to include the identification of areas of contractor support and organic support with the appropriate provisions for each. In addition, there must be: associated plans for the development of formal operational requirements; documents addressing interoperability, life cycle cost, manning, and training; and logistics supportability.

5.3 FOCUS OF MTDs

There are several key criteria against which MTD candidate technologies are evaluated: response to user needs, maturity of these technologies, and potential effectiveness.

5.3.1 User Needs

MTDs focus on addressing critical military medical needs. To evaluate proposed solutions to meet these needs, intense user involvement is required. MTDs place mature medical technologies in the hands of the user and then conduct realistic and extensive military exercises to provide the user an opportunity to evaluate utility and gain experience with the medical capability. The process provides the users a basis for evaluating and refining their operational requirements, for developing a corresponding concept of operations, and ultimately for developing a sound understanding of the military medical utility of the proposed solution before a decision is made to enter into the formal acquisition process. Furthermore, a key objective of MTDs is to provide a residual operational medical capability for the warfighter as an interim solution prior to procurement.

5.3.2 Exploit Mature Technologies

MTDs are based on mature or nearly mature medical technologies (generally at TRL Level 8 or 9, though lower TRL levels may be incorporated in exceptional circumstances). By limiting consideration to mature medical technology, the MTD avoids the time and risks associated with technology development, concentrating instead on the integration, and demonstration activities. This approach permits an early user demonstration on a greatly reduced schedule at low cost.

5.3.3 Potential Effectiveness

The potential or projected effectiveness must be sufficient to warrant consideration as an MTD or the medical capability must address a need for which there is no suitable alternative solution.

5.3.4 Residual Capacity

An additional goal of MTDs is to provide a residual medical capability to further refine CONOPS and to permit continued use prior to formal acquisition, as well as to provide the ability to proceed into formal acquisition for additional medical capability, if required. In other words, medical equipment or systems evaluated in an MTD should be made available following the demonstration for continued operational use or further testing as appropriate.

5.4 MTD APPROVAL PROCESS

Any NATO command, sub-command, body, or nation may request the NTO to consider carrying out an MTD in support of ACO or COMEDS requirements. Each MTD must be managed by ACT or whatever other body (NTO) is assigned by NATO to supervise medical T&E programs. The actual conduct of the demonstration may be done by nations, NATO subordinate commands or other bodies as requested by ACT. All potential user and development organizations should be represented during the MTD planning process. The incorporation of an MTD into the NATO exercise program / Experimentation Program of Work (EPOW) must be requested by ACT and approved through routine NATO processes, as depicted in Figure 5-1.

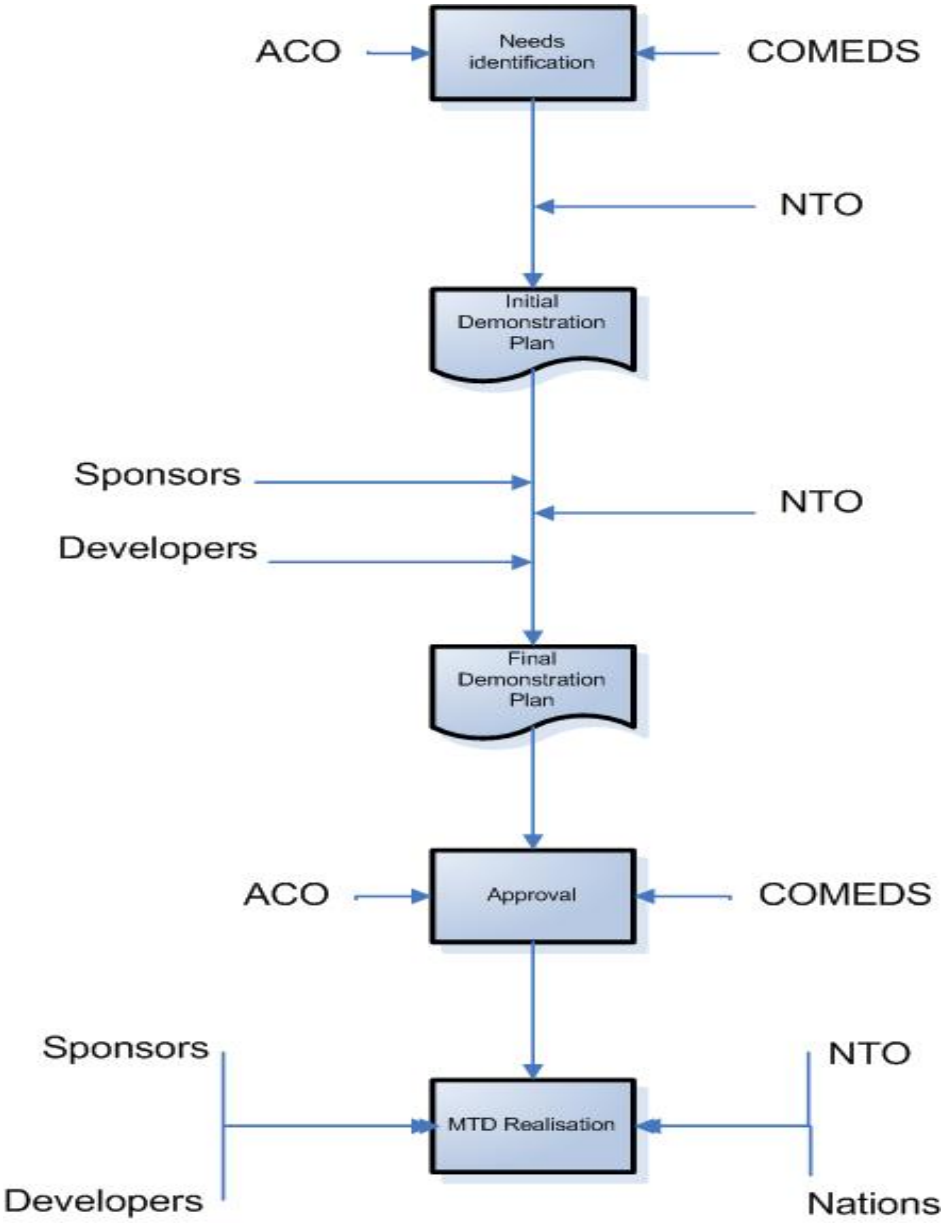

Figure 5-1: MTD Development Process.

5.5 MTD INITIATION AND APPROVAL PROCESS

As noted above in Section 5.2, the primary objective of the MTD process is to accelerate and facilitate the application of mature advanced medical technologies to solve important military problems, as identified by ACO or COMEDS, and thereby provide new operational capabilities which will make a difference to NATO medical support capabilities.

Thus, the basic form of an MTD is represented by a technology program or collection of technology programs which are combined and integrated into a demonstration carried out by NATO to develop or enhance a military medical capability. Generically, this implies identifying significant medical operational shortfalls and matching them up with technology programs ready to focus on a military medical application. Each proposed MTD should arise in response to an identified serious deficiency in some military medical capability or to the presentation of new medical technology which is seen as having the potential to improve NATO medical support, as perceived and articulated by ACO, COMEDS, or other NATO body. Another major MTD goal is to promote NATO interoperability to reach beyond individual national interests and medical capabilities, where this is appropriate.

5.6 GUIDELINES FOR MTD IMPLEMENTATION

5.6.1 Initial Demonstration Plan (IDP)

The Initial Demonstration Plan should clarify the roles and responsibilities of the various parties executing the MTD and to provide unambiguous top-level guidance for carrying out the process. This document is envisioned as an agreement which defines the operational medical capability to be demonstrated, the general approach, the agencies responsible for planning and conducting the demonstration, and the approximate funding and schedule.

The MTD IDP would typically include:

- The overall objective(s) and approach of the MTD;
- Key participants and their primary roles and responsibilities;
- The operational parameters by which military medical effectiveness is to be evaluated;
- The proposed time scale for the MTD and potential follow-on operational medical capability;
- A report of estimated funding required for the MTD; and
- The directions necessary to complete the MTD expeditiously.

5.6.2 Final Demonstration Plan (FDP)

The principal management tool for the MTD is the Final Demonstration Plan, the guidelines for which are given in this document. The FDP is an executive-level document, which will generally be drafted by the NATO Testing Organization. The FDP is a plan; it is not intended to be immutable, as modifications may be warranted from time to time. However, all substantive (i.e., schedule, funding, content, objectives) changes require approval and documentation by the NTO.

The MTD FDP provides a top-level description of the demonstration with sufficient detail that the vital objectives, approach, critical events, participants, schedule, and funding are understood and agreed upon by all

relevant parties. Measures of evaluation, to be considered in addressing both effectiveness and suitability of the capability being evaluated, should be defined.

The content of each FDP should be tailored to meet the diverse needs of that MTD. Specific items which should be addressed within the plan include the following.

5.6.2.1 Objective

An MTD must demonstrate a proposed solution to a critical military medical need. This section should include a discussion of the military medical need, and how it may be met through the use of the equipment or system to be tested. The objectives of the MTD should be spelled out in terms of the need, the new or improved military medical capabilities, and corresponding concept(s) of operations (CONOPS) which would be employed with the medical capability to be demonstrated.

5.6.2.2 Overall Approach

A summary description of the demonstration is to be provided in terms of the broad context, the operational mission, the scenario in which the demonstration occurs, the hardware and software elements involved (including those already within the force structure or under development, as well as, those novel elements of sufficient technical maturity to be deemed low risk), the operational user(s) and their CONOPS, the physical/synthetic location of the demonstration, the number of actual exercises envisioned, the purpose and scope of supporting simulations, and the roles of all of the participants. In addition, the expected time frame and overall funding required to complete the demonstration phase will be summarized.

5.6.2.3 Concept and Technical Approach

A detailed concept of the demonstration, and the planned technical approach to successfully completing it, must be developed early in the planning effort.

5.6.2.4 Scenario(s) and Initial Concept of Operations

After Risk Assessment, as discussed in Chapter 6, the test operational scenario will have been chosen. The operational scenario, or set of scenarios, which provide the context of the demonstration will be described. Typically, the sponsoring user(s) will be responsible for defining the specific mission and scenario(s) to be addressed. The initial CONOPS anticipated for using the medical elements in a military operation for each specified scenario will be defined and described by the user organization, with the assistance of the appropriate T&E manager(s) when necessary.

5.6.2.5 Emerging Technologies

Emerging technologies are hardware and software technologies which are not currently in the force structure, and thus will be the most likely candidates for an MTD. Emerging technologies must be relatively mature (i.e., having an adequate Technology Readiness Level as noted in Chapter 1) with a high probability of providing significant improvements in military medical capability. This section of the plan will identify all of the emerging medical technologies planned to be included in the demonstration (or sequence of exercises). For each emerging technology identified, this section should identify the party responsible for providing it for the demonstration, required dates, anticipated availability, and the expected top-level evaluation characteristics. Metrics to be used for evaluation of the capabilities of the technology being evaluated must be identified in advance, as discussed in Chapter 7.

5.6.2.6 Evaluation Characteristics

There are two general aspects of military medical utility. The first deals with the question of how much the overall medical support can be improved by the use of the evaluated device or system. This question can only be addressed from the integrated perspective of the operational user. The second deals with the issue of how effectively the medical capability under evaluation performs and how suitable is it for use in military operations. To address this second aspect, it is important to define those evaluation characteristics which will be considered to determine efficacy, and what weight will be given to them if there is more than one of them, as discussed in more detail in Chapter 7.

5.6.2.7 Risk Management

Risk management is discussed in detail in Chapter 6, and thus will not be discussed in detail here, though such discussions and decisions must be reflected in the FDP. MTDs are intended primarily to explore operational effectiveness issues of mature medical technologies; therefore, high risk is normally not acceptable. A discussion of the risks will be provided to ensure that all parties understand and accept those risks. Technologies with unacceptable risk should not be included within an MTD.

5.6.2.8 Interoperability

Interoperability refers to the ability of systems, units, or forces to provide services to and accept services from other systems, units, or forces; and to use the services so exchanged to enable them to operate effectively together. It addresses the interfaces to other systems and equipment, as well as logistics and other support. While not all interoperability issues are expected to be resolved during the MTD, the FDP should identify the known issues and specify those which will be resolved. An approach for addressing the remaining issues should be included as well.

5.6.2.9 Equipment

All operational medical equipment which is expected to be involved in the demonstration, including any programmed systems currently in acquisition, will be described. In the event the actual hardware or the necessary quantity thereof is not available, some equipment may participate in the exercise(s) via simulation. The intent is to create as realistic an operational environment as possible, one with sufficient scope to ensure that the lessons learned are valid and can lead to an informed user evaluation decision.

5.6.2.10 Training

It is envisioned that in most cases the emerging medical systems or technologies will actually be operated by operational forces, rather than by contractors, and certainly not by system contractors (see Section 4.6.7). This implies that the personnel designated to conduct the operations during the demonstration must receive adequate training prior to the actual exercises. As a matter of principle, ACT encourages the maximum use of embedded training capability in all equipment. This approach could simplify the task of training the operational forces participating in the MTD. The approach for training (embedded and otherwise) should be discussed.

5.6.2.11 MTD Managers

The MTD managers, the individuals or organizations tasked with actually carrying out the demonstration, will provide the day-to-day direction of the overall project. They will prepare and deliver periodic reports to the NTO and other reviewing authorities. The MTD Managers will bring to the attention of the NTO any potential deviations from the FDP for discussion and resolution, and concomitant modification of the Plan.

5.6.2.12 Acquisition and Contracting Strategy

The overall acquisition strategy for the system or capability being demonstrated should be described. The plan should also include a description of the overall contracting strategy for the MTD and any intended follow-on activity. This strategy should identify each major contract needed to execute the MTD, including a description of the competition plans, contract type, contract options, and schedule. If a sole source contract is planned, the contracting strategy should provide brief rationale and identify the source. Definition of support for additional field testing by the user(s) should also be provided. There is a strong emphasis on streamlined procurement approaches and industry participants. If a technology is to be provided by a national contribution rather than by NATO direct acquisition, this strategy must necessarily follow the prescribed regulations of that nation.

5.6.2.13 Critical Events

A list of all the critical events necessary for successful and timely completion of the demonstration will be provided. These events will serve as decision milestones, with continuation of the MTD contingent upon successful completion. Such events would typically include the approval of the detailed implementation plan, major contract awards, critical pre-demonstration readiness assessment tests, the actual demonstration(s), and final assessment and acquisition recommendations.

5.6.2.14 Residual Operational Medical Capability

MTDs are normally expected to leave behind a limited operational medical capability. In other words, if a demonstration is successful, it should be assumed that the test equipment will remain available to NATO for follow-on use and operational testing. This capability should provide at least a minimum operational medical utility for the user so that it is included in the user's planning and training activities. The scope and role of the residual medical capability (e.g., availability to support a contingency operation) should be described, together with the technical support to be provided (if any) during the two years following completion of the MTD.

5.6.2.15 Transition Plan

Although a detailed transition plan is not required at the initiation of an MTD, it is necessary to consider the implications of a decision to acquire or to utilize during the formulation of the MTD. In addition to the development of the acquisition and procurement strategy and life cycle cost estimate, as described earlier, the Management Plan should also address the assessment of military medical utility. It should describe the basis and methodology (including the role of simulation) for assessing the military medical utility (value to the warfighter). As a minimum, it must assign responsibility and define the schedule for the development of this methodology. In addition, the plan should describe the general approach proposed for achieving adequate supportability for the residual elements as well as for any systems that are proposed to enter directly into production and fielding following a successful MTD. Assuming that the goal is to enter the formal acquisition process at the conclusion of the MTD (which may not be a valid assumption in the NATO environment), this section of the plan should also identify the appropriate acquisition organization. The nature of the transition may vary significantly from one MTD element to another.

5.6.2.16 Safety/Hazards/Environmental Assessment

Since the MTD exercises will likely involve operational personnel utilizing mature advanced medical technology systems, some of which may be left behind as a residual capability, it is necessary to assess the potential safety hazards which might arise in using the equipment, along with likely measures to minimize or

mitigate these hazards, including adequate pre-test familiarization and training. The Management Plan should include a brief paragraph discussing these hazard/safety issues in anticipation of a more detailed, formal assessment (which may be required on a case-by-case basis prior to actual commencement of field exercises). In addition, potential environmental issues should be identified and addressed. Chapter 6 on Risk Assessment may provide assistance in making such an assessment.

5.6.2.17 Schedule

The time scale of an MTD is typically from a few months to four years, not including the two-year follow-on period for extended user operational evaluation required by the MTD criteria in many countries. An overall schedule showing all the major milestones, including critical events will be provided.

5.6.2.18 Funding

Funding for the complete MTD must be identified and committed for all budget years included. However, unlike the case for a formal acquisition decision, out-year funding beyond the MTD and its two-year follow-on phase need not be committed. The funding baseline should include all funds required for completion of the MTD and, separately identified, the funding of supporting scientific and technical efforts which are essential to the MTD. The purpose of the latter is to identify the funding required to assure successful completion of the demonstration. In addition, all relevant prior year funding with relevance to the equipment which is the subject of the MTD (for at least the prior three years), should be given in order to show the heritage of the work being demonstrated and to make clear the degree to which the effort is a new start or based upon prior work. This will also serve to identify the supporting scientific and technical elements and their relevance to the MTD. Only those supporting elements which are direct contributors are to be included in the funding break-out.

5.6.2.19 Approvals

Final top-level approval for each MTD must be given by COMEDS, the Commander(s) of the principal sponsoring user organization(s) or ACO. Such approval is indicated by signature of the Management Plan.

5.6.2.20 Endorsements

In addition to the executive-level approvals listed above, representatives of all other planned participants in the MTD, including co-sponsoring, operational service/support components, sponsors responsible for providing military medical equipment or emerging medical technologies, commanders of ranges or test sites required for the demonstrations, etc., will indicate by endorsement their commitment to providing whatever appropriate participation and/or support is identified in this plan as their responsibility.

5.6.2.21 Modifications

The Management Plan is meant to be a flexible document; it should reflect significant changes in the MTD content which may occur over the course of several years, particularly as new insights are gained. Accordingly, it is expected that the plan will be updated and revised periodically.

Chapter 6 – RISK MANAGEMENT IN THE EVALUATION OF ADVANCED MEDICAL TECHNOLOGY FOR POTENTIAL USE BY NATO

6.1 INTRODUCTION

Risk management is the systematic application of policies, procedures, and practices to the analysis, evaluation, and control of risks. A structured analysis of the risks involved should be an integral part of any test and evaluation program (Chapter 4) for advanced medical equipment or of a MTD (Chapter 5).

Risk management involves the identification and description of hazards and how they could potentially occur, their expected consequences if they occur, and estimations or assessments of the relative likelihood of such occurrence. The estimation of risk for a given hazard is a function of the relative likelihood of its occurrence and the severity of harm resulting from its consequences. Following the identification and estimations of risk, risk management focuses on controlling or mitigating those risks.

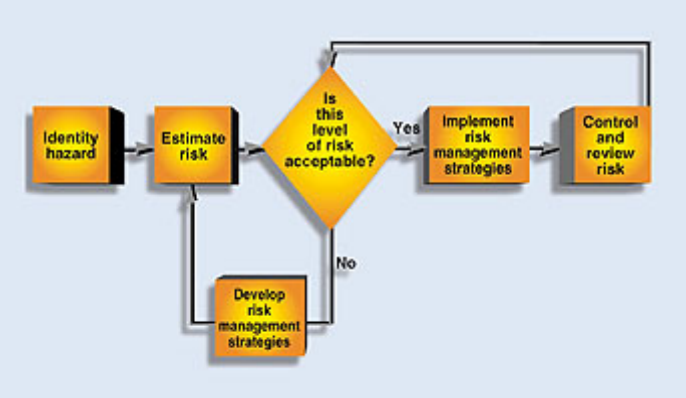

Figure 6-1: Sample Flowchart Showing Risk Management of Identified Hazards.

The management of a single risk consists of four steps, risk detection, risk assessment, risk minimization and risk communication. However, any individual medical device/kit/system, drug/pharmaceutical, biologic, vaccine, combination product, or medical food will have multiple risks attached to it (e.g., using under battlefield conditions rather than in a fixed hospital) and the individual risks will vary in terms of severity. Therefore, the concept of risk management must also consider the combination of information on multiple risks with the aim of ensuring that the benefits exceed the risks by the greatest possible margin for the individual patient and user.

This chapter describes the methods and models related to risk and uncertainty which should be used by the participating nations of NATO and the PfP in the evaluation of advanced medical technology for potential use in the multi-national NATO environment.

6.2 SCOPE

6.2.1 Description of a Risk Management System

A risk management system is a set of activities and interventions designed to identify, characterize, prevent or minimize risks relating to the use of a medical device/kit/system, drug/pharmaceutical, biologic, vaccine, combination product, or medical food, including the assessment of the operational benefits of their use. It does not usually directly involve an economic or cost-benefit analysis, which is more appropriately the goal of a full Health Technology Assessment (This issue is discussed more fully in Chapter 2).

The aim of a risk management system is to ensure that the benefits of a particular medical device/kit/system, drug/pharmaceutical, biologic, vaccine, combination product, or medical food (or any combination of them) exceed the risks by the greatest achievable margin for the individual patient or for the target group as a whole. This can be done either by increasing the benefits or by reducing the risks, but by its definition risk management focuses upon the risk reduction approach. Nevertheless, whenever possible, increases in benefits should also be considered and the characteristics of patients most likely to benefit from treatment better defined.

6.2.2 Risk Communication

Risk communication is an important step in risk management as well as a risk minimization activity (also see Section 4.6.5). Patients, users, planners, logisticians and others who are involved in the use of a new technology need accurate and well communicated information about the risks and benefits associated with both the medical device/kit/system, drug/pharmaceutical, biologic, vaccine, combination product, or medical food and the condition for which it is being used, so that an informed choice can be made about whether the item or system should be adopted. Product information in the form of the Summary of Product Characteristics and Patient Information Leaflets is an important means of informing prescribers and patients about the risks associated with a particular medicine but additional materials may be needed. Risk communication from an operational point of view must be provided to the medical leadership or medical logisticians to assist them in making determinations as to whether to procure and field a new system or product. The mechanism to ensure this communication must be written into the test and evaluation plan, and follow-up efforts must be made to ensure that this evaluation is made a part of the overall test and evaluation process.

6.2.3 Risk Minimization Activities

It is difficult to provide precise guidance on which risk minimization activity should be used in a given situation, as each safety concern needs to be considered on a case-by-case basis.

Direct measurement of risk minimization should be employed whenever feasible. Surrogate measures should be considered when this is not feasible, and such surrogate measures may be used to support interim assessments whilst awaiting direct risk minimization measurements.

For example, for measures based on the provision of information to professionals, descriptive studies or surveys which assess whether the information is being effectively communicated might be appropriate. The use of medical databases might also allow direct measures of how uniformly such advice was being adhered to by reviewing, for example, concomitant medication or the results of laboratory tests. Since such studies are likely to be required with increasing frequency, the availability of such databases will be an ever more important factor in risk management. If the prescribing databases are further linked to patient clinical outcome, a study of the adequacy of the prescribing process could be designed to evolve over time into a full risk reduction study. It is clear that, even when risks are of a type which can be directly measured, ethical and

practical considerations may prevent prospective comparison. It may be scientifically difficult to make direct comparison between a situation with and without the intervention to be assessed and may not be achievable in timescales which allow the lessons learned to be used to improve risk management. In particular this will occur when risks associated with long-term exposure or very rare events are to be reduced.

6.2.4 Ensuring the Effectiveness of Risk Minimization Activities

The definition of risk management requires assessment of the effectiveness of the interventions which form part of the process. It is clearly desirable that activities which may involve substantial investment of effort and resources should be shown to achieve the desired results. In addition, as a medical service measure it is imperative that alternative methods be adopted should a particular risk minimization strategy prove ineffective. Assessment of effectiveness will also increase understanding as to which activities are most appropriate in addressing specific types of safety concerns (this topic is discussed in more detail in Chapter 4).

6.2.5 Definitions Specific to Risk Analysis

The terms “uncertainty”, “risk” and “hazard” are often used interchangeably, but they are not the same:

- **Uncertainty** is the unpredictable possibility of occurrence of an event.
- **Risk** can be defined as the combination of the probability of an event **and** its consequences[1]. Risk also can be defined as the combination of the probability of occurrence of harm **and** the severity of that harm[2].
- **Hazard** is the potential source of harm[3].

Harm is a physical injury or damage to the health of people or damage to property or the environment.

Risk Management is a process for managing the incidence of risk, as defined above. In the safety field it is generally recognized that consequences are only negative and therefore the management of safety risk is focused on prevention and mitigation of harm. Because risk cannot be completely eliminated, the risk that remains must be managed.

6.2.6 Levels of Risk Management

In every medical service, risk management activities broadly take place simultaneously at different hierarchy levels:

- **Strategic Level –** This level encompasses risk management functions performed by ACT or the NTO during their evaluation of advanced technology for adoption to support NATO forces. For instance, the definition of risks, ascertaining the institution’s risk appetite, formulating strategy and policies for managing risks, and establishing adequate systems and controls to ensure that overall risk remain at acceptable level and the rewards compensate for the risk taken.
- **Operational Level** – This level encompasses risk management within the ACO or theatre surgeon/ medical advisor area. Generally the risk management activities performed by middle management or units devoted to risk reviews fall into this category.

[1] ISO/IEC Guide 73:2002.

[2] ISO/IEC Guide 51:1999.

[3] ISO/IEC Guide 51:1999.

- **Tactical Level –** This level encompasses risk management within the Roles 1 – 3 facility areas where risks are actually created. Generally the risk management activities performed by 'On-the-line' management or units devoted to risk reviews will fall into this category.

6.3 RISK ANALYSIS

6.3.1 General Approach

There is a wide variety of methods and models available for risk and uncertainty analysis of medical device/ kit/systems, drugs/pharmaceuticals, biologics, vaccines, combination products, or medical foods. These include simple techniques and sensitivity analysis. Each, if used properly, can give scientifically sound results, but first a word of caution – based on the collective experience in risk management within the government and in the private sector, it is fair to say that the sophistication and underlying theory of many popular models often far exceeds the quality of the basic data inputs.

There is simply no substitute for taking the time and effort to understand the technical risks and challenges in developing and producing sophisticated defence systems. Historical analogies must be obtained. Information from subject matter experts must be elicited. Risk and uncertainty analysis cannot be relegated to an eleventh hour exercise based on flimsy inputs.

The most important part of the process of estimating risk and uncertainty, and probably the most difficult, is data collection and analysis. All variables potentially affected by risk and uncertainty first need to be identified. These variables often include simple ratios and factors as well based on analysis.

There are a variety of analytic approaches that are used by systems engineers. Analytic approaches used for investigations including function and task analysis, heuristic analysis, and expert reviews. These approaches can be applied within more comprehensive approaches such as Operational Analysis (which DOES NOT mean Operational Research in the military used form), Analysis of Similar Systems, Failure Modes Effects Analysis (FMEA), Fault Tree Analysis (FTA), Critical Incident Technique, Hazard and Operability Studies (HAZOP), and others. Detailed discussion of these techniques is beyond the scope of this publication.

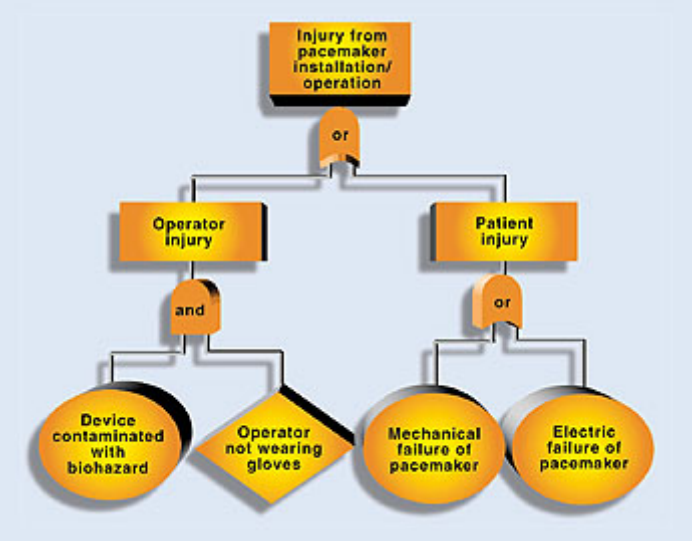

Figure 6-2: A Partial Fault Tree Analysis for a Pacemaker.

6.3.2 Collecting Data for Risk Analysis

Data is the raw material of risk and uncertainty analysis. It is critical to every estimate. Without good, solid data, whether based on historical analogies or on sound medical understanding of the acquisition at hand, the risk and uncertainty estimate will be viewed as merely a guess or an opinion of the analyst. The more solid the data, the better will be the estimate. This issue is further discussed in Chapter 7.

6.3.3 Modeling and Simulation

Modeling and Simulation (M&S) can be used as a tool to support the development and operational use of new concepts and systems for the future. M&S also help to better train and use existing forces and equipment and to improve operations in the new environment. The simulation of the Military Decision Process is a critical part in the use of M&S for this purpose. Modeling and Simulation will be not discussed in this document[4].

6.3.4 Ergonomic (Human Factors) Testing

A device that is easy for one person to use safely and effectively might present problems for another person. Similarly, a device that is easy for a certain group of users to use safely and effectively could be difficult for another group. Users need devices that they can use safely and effectively, and an evaluation of this generic "usability" must be made an integral part of the T&E process.

A well-designed user interface will facilitate correct actions and will prevent or discourage actions which could result in hazards. The user interface includes all components of a device with which users interact while using it, preparing it for use (e.g., calibration, set-up, unpacking), or performing maintenance (e.g., repairing, cleaning). It includes hardware features that control device operation such as switches, buttons, and knobs and device features that provide information to the user such as indicator lights, displays, auditory, and visual

[4] For more information on the subject of simulation, see RTO-EN-017 AC/323(SAS-032)TP/26 "Simulation of and for Military Decision Making" and the RTO "Simulation Resource Library (SRL)".

alarms. The user interface also includes the logic that directs how the system responds to user actions including how, when, and in what form information (feedback) is provided to the user. An important aspect of the user interface is the extent to which the logic of information display and control actions is consistent with users' abilities, expectations, and likely behaviors.

Increasingly, user interfaces for new medical devices are computer-based. In these cases, interface characteristics include: the manner in which data is organized and presented, control and monitoring screens, screen components, prompts, navigation logic, alerting mechanisms, data entry requirements, help functions, keyboards, mice, and pointers. The size and configuration of the device are important parts of the user interface, particularly for hand-held devices. Device labeling, packaging, training materials, operating instructions, and other reference materials are also considered part of the user interface.

An important concept pertaining to user interface use-safety is error tolerance. Error tolerance is the quality of a user interface which prevents or mitigates dangerous or disastrous consequences when an error occurs. Humans make errors. Some kinds of error can be anticipated and are essentially unavoidable – such as inadvertently pressing an adjacent key on a keypad, or bumping the keypad inadvertently while doing other tasks. A good device design will increase the likelihood that the design is tolerant of errors that are likely to be made by users. There are many ways to do this; one example is the placement of a shield over the button that initiates a beam of radiation to prevent inadvertent activation. The logic of device operation can also determine its degree of error tolerance. For example, some devices include "interlocks" or mechanisms that prevent a critical process from being initiated without users verifying their intent to initiate it or necessitating extra control steps to be performed before proceeding. In other cases, devices can be designed to do tasks that users do not do well, such as timing certain steps in operational-testing procedures, remembering set-up parameters, or test dates, or performing calculations. For complex procedures, devices can prompt users to perform the appropriate action at critical points in the procedure.

6.3.5 Operational Testing

Operational testing is a powerful technique used to assess the user's interaction with a product. This technique can also be used to identify and understand previously unanticipated or poorly understood use scenarios resulting in hazards if care is taken to focus on the safety and effectiveness perspectives. The central advantage of operational testing is that device use is realistic and the results of the process are more representative of actual use than results obtained through analytic approaches.

Operational testing involves the systematic collection of data from users (participants) using a device (or device component) in realistic situations. Data is obtained in a variety of ways, including user feedback, manual and automated measures of user performance, and observation. Often, the most convenient data collection methods focus on subjective user feedback. User feedback includes descriptions by test participants of difficulties encountered, good and bad aspects of the device user interface characteristics, including the logic of device operation, and suggested changes. Careful collection of subjective assessment of device use can identify problems that were noticed by test participants ("concerns" or "close calls") but which did not manifest themselves as errors during use and which were not identified in objective performance measures. (Chapter 7 discusses this issue in more detail.)

Objective user performance measures include the type and number of errors, time required to do tasks, requests for help, accuracy, and the success or failure on individual tasks and overall performance. The application of specific, objective user performance measures enhances and focuses subjective user feedback. Performance measures are particularly useful for complex devices, where users might not be aware

of (and therefore unable to evaluate) potentially hazardous use scenarios. These measures are also important for military-use devices where users are often not aware that they are inadvertently affecting the performance or accuracy of the device in some way. Outlier data from performance measures is often informative and should be investigated to determine the nature and pattern of the use scenarios associated with them.

Operational testing can be done in a variety of ways in various degrees of complexity and formality, one mechanism of which is the MTD (See Chapter 5). However it is done, it should include the following:

- An overall goal of improving the usability, including safe and effective device use;
- Test participants represent intended users;
- Test participants do real tasks, particularly tasks which will indicate whether safe and effective use is achieved;
- A focus on high risk use scenarios;
- Testers who observe and record important aspects of what test participants do and say (participants can also respond to questionnaires, or be interviewed following the use of the device); and
- Data collected to support the identification of potential use-related hazards and the development of specific recommendations to address them.

The validity of testing depends on the extent to which realistic or simulated environments are used during the testing. For example, in clinical settings users must perform multiple tasks simultaneously. These tasks involve individual devices, multiple devices, and duties unrelated to device use. Users must constantly trade-off accuracy for speed. In battlefield environments, users might be distracted or have medical conditions that affect their abilities to interact with the device. Users can also drop devices or expose them to various temperatures and humidity levels, beyond the designated design criteria. Clinical and operational users might try to cut costs. There are many aspects of the use environment that can affect device use.

The amount of thinking and concentration a person exerts while using a device is called mental workload. The mental workload imposed on users by the environment in which they use devices can exceed their abilities to use devices properly. For instance, in an operating room, there could be too many alarms on different devices for an anesthetist to be able to identify the source of any single alarm. Mental workload is often used synonymously with mental “stress”. There can be a physical component to workload associated with medical device use (physical workload) that also adds to the stress experienced by the user. Under high stress levels -especially under battlefield conditions-, the user is distracted and will have less time to make decisions, consider multiple device outputs, follow complex operating logic, or physically manipulate device components. Devices that can be used safely under conditions of low stress (i.e., low workload) could be difficult or dangerous to use under conditions of high stress.

6.3.6 Cost and Budget Risk

6.3.6.1 Cost Risk

The baseline cost estimate contains modeling uncertainty while the risk-adjusted cost estimate contains both modeling uncertainty and technical uncertainty and risk. The risk-adjusted probability distribution will therefore have a higher mean value and a higher variance than the baseline estimate. The difference in mean or expected values of the two distributions is cost risk. This value is usually expressed in monetary rather than percentage terms. It accounts for the cost impact of unfavourable outcomes in a major acquisition programme. Aggregate cost risk can be allocated to any cost breakdown structure element, as appropriate.

6.3.6.2 Budget Risk

Budget risk is the probability that the actual cost of a medical device/kit/system, drug/pharmaceutical, biologic, vaccine, combination product, or medical food acquisition program will end up exceeding a given budget. In this case, the budget is set at the mean value of the risk adjusted cost estimate. Since the budget is finite, there is a certain probability it will be exceeded. A low budget implies a high probability of an overrun while a high budget implies a low probability of an overrun. It will be up to the decision maker to decide where he/she wants to set the budget, and how much risk he/she is willing to take in this regard.

6.3.6.3 Cost and Budget Risk for Military Used Systems

Cost risk and budget risk are generally a part of projects to introduce available medical devices, kits and systems. It is also a part of projects to produce medical devices, kits and systems. Cost risks and budget risks will not be further discussed in this document[5].

6.3.7 Time Risk

One risk of potential significance is that of time risk. The demand for speed in carrying out evaluations, or for speed in fielding items, may lead to a demand to accept higher risks in other areas, as described above.

6.4 RISK MINIMIZATION

6.4.1 Requirements of Advanced Medical Technology for Potential Use by NATO

6.4.1.1 General Requirements

Medical device/kit, drug/pharmaceutical, biologic, vaccine, combination product, medical food must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will enhance and not compromise the safety of patients, or the safety and health of users or, where applicable, other persons. Medical devices, kits and systems must contribute to providing optimum care for the patients under operational conditions which apply the principles of MC 326/2 and AJP-4.10 (A).

As a part of a full operational risk analysis, it may be that any risks which may be associated with intended use of the medical device/kit, drug/pharmaceutical, biologic, vaccine, combination product, medical food constitute acceptable risks when weighed against the benefits to the patient or the operation and are compatible with a high level of protection of health and safety.

The evaluation of the risks of new technology should include:

- Reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for user and patient safety); and
- Consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, or other users).

The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

[5] For more information see RTO-MP-096 AC/323(SAS-036)TP/27 “Cost Structure and Life Cycle Cost (LCC) for Military Systems”.

- Eliminate or reduce risks as far as possible (inherently safe design and construction);
- Where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated; and
- Inform users of the residual risks due to any shortcomings of the protection measures adopted.

6.4.1.2 Requirements for Safety and Performance of Advanced Medical Technology

To introduce an available or produce a new medical device/kit, drug/pharmaceutical, biologic, vaccine, combination product, medical food, it is necessary to have an accurate and complete understanding of how it will be used. Understanding and optimizing how people use and interact with technology is the subject of human factors engineering (HFE). HFE considerations important to the development of medical devices include device technology, the users, the environment in which the technology will be used, how dangerous device use is, and how critical the device is for patient care.

Several general HFE concepts should be considered before proceeding with a discussion of HFE approaches in the context of risk management.

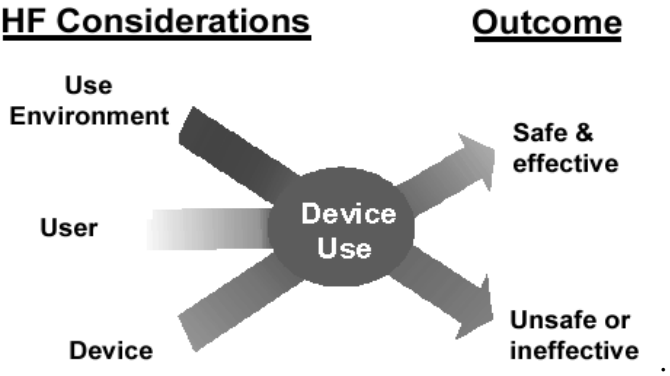

Figure 6-3: HFE Considerations and Outcome.

To avoid harm the US and EU have issued comprehensive directives of design and manufacturing requirements for safety and performance, some of which are relevant to each medical device/kit, drug/pharmaceutical, biologic, vaccine, combination product, medical food.

These requirements should concern:

- Chemical, physical and biological properties.
- Infection and microbial contamination.
- Manufacturing and environmental properties.
- Devices with a diagnostic or measuring function.
- Protection against radiation.
- Requirements for medical devices connected to or equipped with an energy source.
- Protection against mechanical risks.
- Protection against the risks posed to the patient by supplied energy or substances.

- Protection against the risks posed to the patient by devices for self-testing or self-administration.
- Information supplied by the manufacturer.
- Performance evaluation including, where appropriate, clinical and operational or field test evaluation.

Annex B discusses this issue in more detail.

6.4.1.3 Operational Requirements for Potential Use of Advanced Medical Technology by NATO

Every medical device/kit, drug/pharmaceutical, biologic, vaccine, combination product, medical food for potential use by NATO must contribute to providing optimum care for the patients under operational conditions which apply MC 326/2 and AJP-4.10 (A). To obtain benefits under operational conditions it might be necessary to accept potential adverse effects. The minimization of those potential adverse effects has to consider during all phases of Test and Evaluation (T&E) or Modeling and Simulation (M&S). Chapters 4, 5 and 7 discuss this issue in more detail.

6.4.1.4 Organizational Requirements for Potential Use of Advanced Medical Technology by NATO

To introduce an available medical device/kit, drug/pharmaceutical, biologic, vaccine, combination product, medical food, it is necessary that NATO have the organizational structures, the responsibilities of the managerial staff and their organizational authority where the usability, the quality of manufacture, logistics and support of the products are provided.

To field a new medical device/kit, drug/pharmaceutical, biologic, vaccine, combination product, medical food, it is necessary to have in particular:

- The organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned;
- The methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform; and
- The procedures for monitoring and verifying the design of the products, including the corresponding documentation the inspection and quality assurance techniques at the manufacturing stage a Concept of Operations (CONOPS) to set forth how it could be used in the environment for which it designed.

But it must be reiterated that it is neither the intent nor is it within the scope of this document to recommend or to build a fixed organizational structure to carry out these functions.

Chapter 7 – THE EVALUATION PROCESS

Whether used in a T&E process for a specific item of equipment, or in an MTD process to evaluate the benefits of introducing a medical device or system into the NATO Multi-National Medical Care System, the Evaluation process must follow essentially the same pattern, as shown in Figure 7-1.

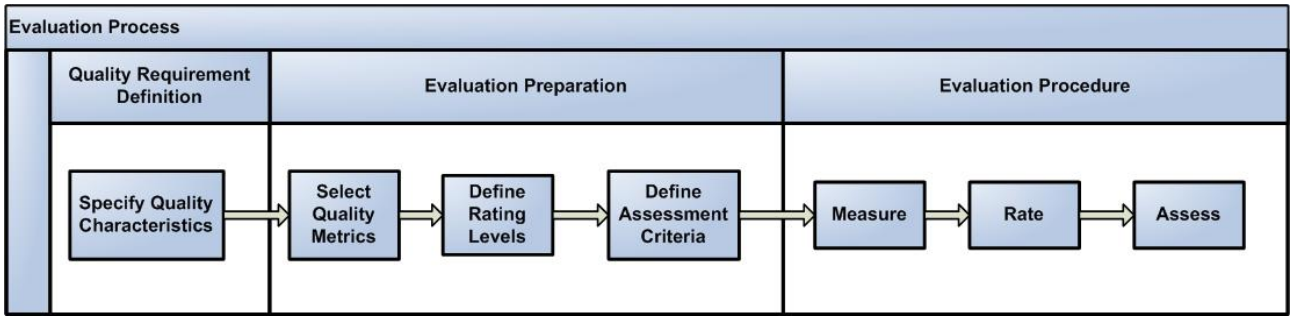

Figure 7-1: The Evaluation Process.

7.1 THE EVALUATION PROCESS

The evaluation process consists of three stages, as noted in the sections below.

7.1.1 Quality Requirements Definition

The purpose of the initial stage is to identify required testable operational characteristics and possible sub-characteristics, in order to allow the development of a testing matrix. The NTO may consider at this stage the preparation of a Requirements Document to ensure inclusion of all testable components (see Annex C).

7.1.2 Evaluation Preparation

The purpose of the second stage is to prepare the basis for evaluation. This stage consists of three components, as noted in the sub-sections below.

7.1.2.1 Metrics Selection

The manner in which operational characteristics have been defined does not allow their direct measurement, therefore this can only be accomplished by measuring their attributes. The need exists to establish metrics that correlate to the characteristics of the device. Every quantifiable feature of the device and every quantifiable interaction of the device with its environment that correlates with a characteristic can be established as a metric.

7.1.2.2 Rating Levels Definition

Quantifiable features can be measured quantitatively using metrics. The result, the measured value, must be interpreted as a rated value.

7.1.2.3 Assessment Criteria Definition

To assess the appropriateness of the device in its proposed environment, the results of the evaluation of the different characteristics must be summarized. The evaluator has to prepare a procedure for this, using, for instance, decision tables or weighted averages. The procedure usually will include other aspects such as time and cost that contribute to the assessment of appropriateness of the device in a particular use environment.

7.1.3 Evaluation Procedure

The last step of the Evaluation Process Model is refined into three components, namely measurement, rating and assessment.

7.1.3.1 Measurement

For measurement, the selected metrics are applied to the device. The result is values on the scales of the metrics.

7.1.3.2 Rating

In the rating step, the rating level is determined for a measured value.

7.1.3.3 Assessment

Assessment is the final step of the device evaluation process where a set of rated levels are summarized. The result is a statement of the appropriateness of the device. Then the summarized evaluation is compared with the other aspects such as time and cost. Finally managerial decision will be made based on the managerial criteria. The result is a managerial decision on the acceptance or rejection, or on the release or non-release of the device.

7.1.4 Testable Characteristics Identification

If the efficacy of a device is to be evaluated, a structured set of testable characteristics is needed, plus a method for evaluation and a quantitative scale of measures.

Several high-level approaches to measuring the efficacy of devices exist. These approaches are based on the idea that there are a number of important high-level factors of devices that should be measured. These factors are determined by lower-level criteria which are supposed to be much easier to measure than factors; for this reason, metrics are proposed as criteria.

Especially for modern Health Care Devices, it is not convenient to look for a global efficacy profile (a list of values obtained by assigning a score to each sub-characteristic). A broad classification of Health Care Devices into five categories (Networking, Archiving, Image Processing, Clinical, Administration), according to their functionality, allows us to obtain five separate profiles, which are easier to handle than would be a global value in the evaluation process. The profiles result from the application of the model as a checklist to define the relevance of each sub-characteristic to each class.

The proposed approach, for the evaluation of Health Care Devices, is based on the ISO/IEC 9126, which describes software quality as a function of six characteristics:

- Functionality;

- Reliability;
- Efficiency;
- Usability;
- Portability; and
- Maintainability.

This decomposition reflects the users' view and introduces the concept of quality in use: users are mainly interested in using the system, and evaluate it mostly from the viewpoint of the performance and the service it provides, rather than on the basis of internal aspects or the development process. The proposed approach suggests a further decomposition of each characteristic into a set of sub-characteristics: these sub-characteristics are a step closer to the quantitative, technical aspects of a device.

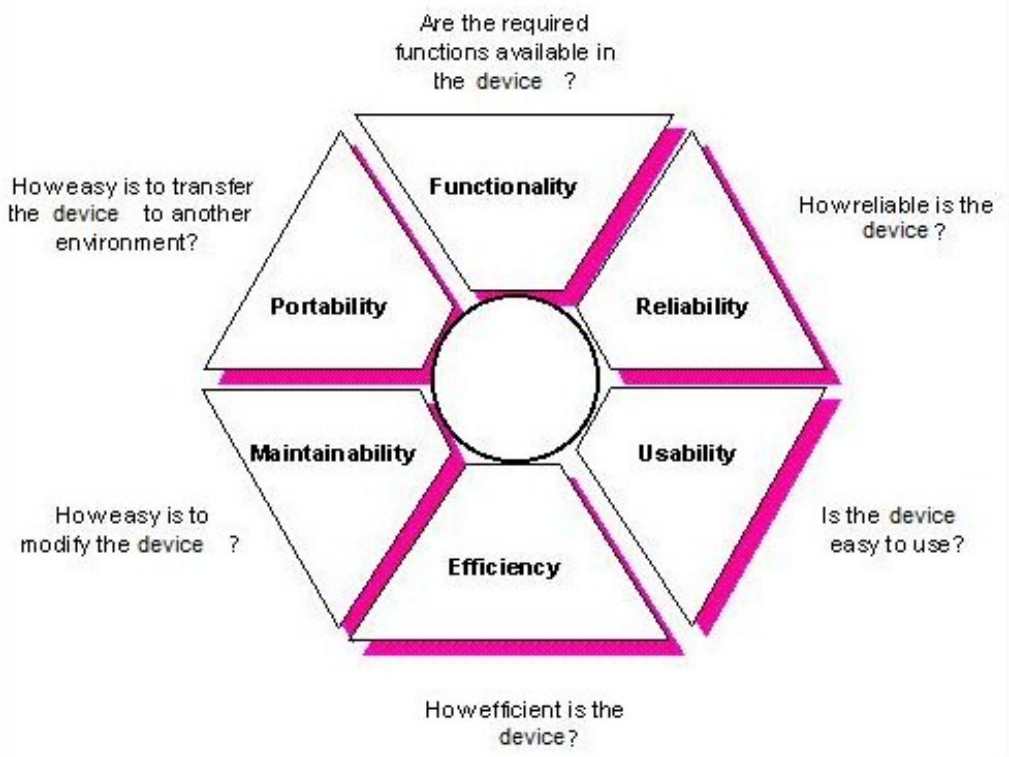

Figure 7-2: An Approach to a Functional Analysis of Health Care Devices[1].

7.1.5 Functionality

Functionality is a set of attributes which bear on the existence of a set of functions and their specified properties. The functions are those which satisfy stated or implied needs:

- **Suitability:** Attributes which bear on the presence and appropriateness of a set of functions for specified tasks.

[1] ISO/IEC 9126.

- **Accuracy:** Attributes which bear on the provision of right or agreed results or effects.
- **Interoperability:** Attributes which bear on the tested item's ability to interact with specified systems.
- **Security:** Attributes of a device which bear on the tested item's ability to prevent unauthorized access, whether accidental or deliberate.

7.1.6 Reliability

Reliability is a set of attributes which bear on the capability of the device to maintain its level of performance under stated conditions for a stated period of time:

- **Maturity:** Attributes of the device which bear on the frequency of failure by faults.
- **Recoverability:** Attributes of the device which bear on the capability to re-establish the tested item's level of performance and on the time and effort needed for this re-establishment.
- **Fault Tolerance:** Attributes of the device which bear on the tested item's ability to maintain a specified level of performance in case of faults or of infringement of its specified interface.

7.1.7 Usability

Usability is a set of attributes which bear on the effort needed for use, and on the individual assessment of such use, by a stated or implied set of users:

- **Learnability:** Attributes of the device which bear on the users' effort needed for learning its application.
- **Understandability:** Attributes of the device which bear on the users' effort needed to recognize the logical concept and its applicability.
- **Operability:** Attributes of devices which bear on the users' required effort for operation and operation control.

7.1.8 Efficiency

Efficiency is a set of attributes which bear on the relationship between the level of performance of the device and the amount of resources used, under stated conditions:

- **Time Behaviour:** Attributes of the device which bear on response and processing times and on throughput rates in performance of its function.

7.1.9 Maintainability

Maintainability is a set of attributes which bear on the effort needed to make specified modifications, including repairs:

- **Stability:** Attributes of the device which bear on the risk of unexpected effects of modifications.
- **Analyzability:** Attributes of the device which bear on the effort needed for the diagnosis of deficiencies or causes of failures, or for identification of parts requiring to be modified.
- **Changeability:** Attributes of the device which bear on the effort needed for modification, fault removal or for environmental changes.
- **Testability:** Attributes of the device which bear on the effort needed for validating the modified part.

7.1.10 Portability

Portability is a set of attributes which bear on the ability of the device to be transferred from one environment to another:

- **Installability:** Attributes of the device that bear on the effort needed to install it in a specified environment.
- **Replaceability:** Attributes of the device that bear on opportunity and effort using it in the place of specified other system in the same environment.
- **Adaptability:** Attributes of the device that bear on the opportunity for its adaptation to different specified environments without applying other actions or means than those provided for this purpose.
- **Conformance:** Attributes of the device that make the device adhere to standards or conventions relating to portability.

7.2 TABLES OF CHARACTERISTICS OF ATTRIBUTES

The following tables describe the above attributes for each characteristic. The attributes are classified both for procurement and for operational testing of a medical device.

These attributes are indicative and not exhaustive. The tables have to be used as a means to comprehend the characteristics for the evaluation. The evaluator has to define the appropriate attributes, during the quality requirements definition process, in order to conduct a valid evaluation of the medical device or product.

Table 7-1: Evaluation of a Health Care Device or System for Procurement

EVALUATION OF A HEALTH CARE DEVICE OR SYSTEM FOR PROCUREMENT		
Functionality	Suitability	The percentage of desired functionality that is actually present in the device.
	Accuracy	The number of functions implemented compared to the functions written in the user's manuals.
	Security	Estimation of the probability that with a certain amount of effort (time, money, equipment) the device security measurements will not be bypassed.
Reliability	Fault Tolerance	Estimation of the probability of maintaining a specified level of performance in case of faults within a certain period.
Efficiency	Time Behaviour	• The time that passes between the start and finish of a process. • Number of information items which can be processed sequentially. • Number of processing tasks of a certain type that the user can perform during a certain period with a certain usage load. • Maximum time a certain internal processing task occupies with a certain usage load.

EVALUATION OF A HEALTH CARE DEVICE OR SYSTEM FOR PROCUREMENT		
Efficiency	Time Behaviour	• The speed of processing by measuring the elapsed time between the beginning of process requirement and gaining the result of the process. • The speed of processing by measuring the elapsed time between the end of inquiry or request to the device and the start of response.
Usability	Learnability	• The proportion of examples, index entries, illustrations and tables per command, and/or the proportion of references, chapters, sections and sub-headings per page. • The degree of availability of reference manuals, on-line user's manuals and self-tuition documents such as operation manuals, grammar reference materials, installation manual, etc. • For a given range of functions, the degree of availability of materials for pre-learning (before use of the system), such as self-tuition manuals, automated tutorials or instructions. • For a given range of functions, the ratio of the number of available learning functions to the number of necessary learning functions. • For a given range of functions, the ratio of the number of available help functions to the number of necessary help functions.
	Understandability	• The proportion of functions which can be explained by using clear, familiar models to illustrate concepts. This represents the degree to which the functions and conventions of a device are explained through models using familiar concepts from the everyday world. • The proportion of functions presented to the users through demonstration.
	Operability	• The operability of the device is compared to the operability of a pre-determined sample product. • The number of steps for set-up installation operation which require human interaction (for everyday use). • The ratio of number of set-up performances available and the total number of performances: availability of set-up installation restart, availability of set-up installation confirmation functions. • The average time required to set up the device or system. • The number of points at which users can make a pause and from which the installation operation can be restarted. • The number of types and amount of resources including system, hardware, software and personnel to be employed for installation. • The number of steps for installation confirmation operation which are necessary to validate that the device or system has been successfully installed and is ready to be used adequately.

EVALUATION OF A HEALTH CARE DEVICE OR SYSTEM FOR PROCUREMENT		
Usability	Operability	• The ratio of operating commands having default values to the total number of operating commands. • The proportion of operating commands having uniform formats, which are based on common-sense and comprehensible rules. • The proportion of system message terms that are standardized. • The proportion of system messages from device or system in which causes and corresponding action are clearly identified by the user who received those messages. • The proportion of functions for which operating methods can be selected to correspond to the user's level of skill. • The proportion of types of screen-manipulating operations using common basic conventions or patterns. • The proportion of input/output screen formats designed with standardized formats in which the position and form of input/output fields are commonly laid out. • The number of keystrokes of operation required by the user to carry out the work. • The ratio of strokes required to repeat an operation to the strokes required for the first operation to perform a specific task. • The ratio of available guide functions to the required ones for a given set of functions.
Portability	Installability	• The installation effort in man-months. • Parameter correction ratio which is to be changed by transferring the device. • Output list correction ratio which is to be changed by transferring the device.
	Replaceability	Function ratio to be changed by transferring the device.
	Adaptability	• Mean effort needed to adapt a unit volume of the device to a different specified platform. • Applicable ratio of operation manual and procedure without changing the device.
	Conformance	Conformance ratio in which the device is in conformance with the laws, provisions and conventions.
Maintainability	Changeability	Fulfilment degree of product documents that are usable in the maintenance stage.
	Testability	• Effort needed to test one unit volume of the device with a certain testing coverage degree. • Number of test cases that have to be made to test a unit volume of the device with a certain testing coverage degree.

Table 7-2: Operational Test of a Medical Device

OPERATIONAL TEST OF A MEDICAL DEVICE		
Functionality	Suitability	• The ratio of functions that has been changed during the operational tests (change includes addition, modification, and deletion). • The number of improvement requests for functions from users during the operational tests.
	Accuracy	The ratio of incorrect processed transactions to the total of presented transactions.
	Interoperability	• The effort needed to realize interoperability per unity of size of interoperability. • The ratio of observed standards to the standards made in the device or among the device.
	Security	The ratio of confidential information that have access histories to all confidential information.
Reliability	Maturity	• Average time that passes between two failures. • The mean time between one failure occurrence and succeeding failure occurrence during a given period of time. • The ratio of number of faults in a released product to the unit volume of a released product. • The ratio of faults corrected up to a point of time to the estimated number of faults initially present in a product. • The ratio of number of faults in a product to the unit volume of a product (e.g., design specification, functionality specification). • The ratio of test volume (e.g., number of test cases) conducted during the development phase to the unit volume of a product tested and released. • The ratio of amount of tests actually carried out up to a point in time to the total amount of tests to be carried out.
	Recoverability	• Average time needed to recover the damaged device. • The ratio of automatically resolved failures (by the device) to the total number of failures for which automatic recovery would be preferred. • The mean time between occurrence of device breakdown and completion of recovery from breakdown. • The mean time between occurrence of device breakdown and completion of recovery and restart from breakdown. • The mean time between completing recovery of device breakdown and completing restart after breakdown. • The mean time between introduction of a fault and removal of the fault.

OPERATIONAL TEST OF A MEDICAL DEVICE		
Reliability	Fault Tolerance	• The number of times processing halted due to incorrect use within a certain period. • The extent to which it is possible to halt processing due to incorrect use. • The ratio of number of observed breakdowns to the number of observed failures through a given period of time. • The ratio of number of erroneous operations or inputs detected by a device to the number of erroneous operations or inputs conducted during a given period of time.
Efficiency	Time Behaviour	• The average and maximum time a user needs for a certain processing task, with a certain usage load. • Average time a certain internal processing task occupies with a certain usage load. • The amount of jobs processed in a unit of time. • The number of transactions done in a unit of time.
Usability	Learnability	• The time an average end-user from the target group needs to learn to work with the device, plus the amount of guidance time needed. • The proportion of user claims resulting from incorrect operations caused by misunderstanding of the programs or manuals. • The usage time from the first usage until the usage at which the operating time is shortened to x/y of the first use to perform the same specific task. • The ratio of time required to learn one operation for a specific task and operation time.
	Understandability	• The understandability of the instructions, menus, commands, pictograms, icons, help information, instructions, manuals, etc., of the device as rated by the user. • Rating of the readability of the device (on-screen messages, documents, pictograms, etc.).
	Operability	• The extent to which the device presents functionality to the user without hindrance, as judged by a team of experts in this field. • The extent to which the device presents functionality to the user without hindrance, as judged by users after a period of use. • The sum of time required for the installation process, including preparations, execution of environment set-up and verification. • Average time interval between one operation error (human error operation) and the next. • The time required for the operation that is ultimately reduced and cannot be reduced anymore by further improvements.

OPERATIONAL TEST OF A MEDICAL DEVICE		
Usability	Operability	• The average time between the input of the system shutdown command at the beginning of shutdown operation and the time when shutdown is completed. • The ratio of command/data entries that can be cancelled to the total command/data entries. • The ratio of number of actually implemented means to required ones which are provided to emphasise expressions to the user for a given set of functions. It is considered that colour, sound, brightness, and animation are means to emphasise expressions. • The elapsed time from the user input request or command to the nearest response to that request by the device or system. The first response to the request may be a state or progress report expressing that device or system is processing the request. At least mean, minimum and maximum time should be measured. • The elapsed time from the current display on screen after request to change, to the next complete display on screen. At least mean, minimum and maximum time should be measured.
Maintainability	Stability	The ratio of new faults made at the revision.
	Analyzability	• The ratio of number of failures where users correctly recognized the fault positions to the number of detected failures caused by the faults of the device as a consequence of the maintainer analysing the failures. • Mean time needed to analyse a failure, and to discover any faults arising from this failure, and separate the positions to be repaired by the maintainer who received the failure report.
	Changeability	• Average amount of effort needed to modify the device, per unit volume of the modification. • Mean effort needed to repair a defect in the device. • Mean time from receiving the failure report to sending the corrected device in fault correction. • Mean time from the failure occurrence to the restoration for end users. • Mean work time for correcting the discovered device fault to be corrected in fault correction, in consequence of analysing the failure.
	Testability	• Mean user’s work time to verify the fault correction. • Mean maintainer work time to test the fault correction after correcting the fault.

Annex A – RECOMMENDED NATO BIOMEDICAL TECHNOLOGY READINESS LEVELS (TRLs)

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
1) Basic Principles Observed and Reported in the Context of a Military Capability Shortfall **Definition:** Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies. Scientific research begins to be evaluated for military applications. Some Scientific Research begins to be translated into technology's basic properties. Examples of R&T outputs might include paper studies of a technology's basic properties and potential for specific utility.					Hardware/Software (HW/SW) technology explored. Basic theories applied to IT field suggest promise. Conceptually, it may be possible to use Informatics Technology already at a higher level of readiness to begin to address medical needs, thus being placed at TRL Level 1 for biomedical purposes.
	TRL 1 Decision Criterion: Scientific literature reviews and initial Market Surveys are initiated and assessed. Potential scientific application to defined problems is articulated.	**TRL 1 Decision Criterion:** Scientific literature reviews and initial Market Surveys are initiated and assessed. Potential scientific application to defined problems is articulated.	**TRL 1 Decision Criterion:** Scientific literature reviews and initial Market Surveys are initiated and assessed. Potential scientific application to defined problems is articulated.	**TRL 1 Decision Criterion:** Scientific literature reviews and initial Market Surveys are initiated and assessed. Potential scientific application to defined problems is articulated.	**TRL 1 Decision Criterion:** Identification of the potential medical solution to mission need has been accomplished. Medical Informatics data and knowledge representation issues are defined.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
2) Technology Concept and/or Application Formulated **Definition:** Invention begins. Once basic principles are observed, practical applications can be postulated. The application is speculative and there is no definitive proof or detailed analysis to support the assumptions. Example: R&T outputs are still mostly paper studies.	Intense intellectual focus on the problem with generation of scientific "Paper Studies" that review and generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues.	Intense intellectual focus on the problem with generation of scientific "Paper Studies" that review and generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues.	Intense intellectual focus on the problem with generation of scientific "Paper Studies" that review and generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues.	Intense intellectual focus on the problem with generation of scientific "Paper Studies" that review and generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues.	Intense intellectual focus on the problem with generation of scientific "Paper Studies" that review and generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues. Hardware and Software concept of use begins development. Overall system concepts are documented by flowcharting or other system descriptions.
	TRL 2 Decision Criterion: Hypothesis (es) generated. Research plans and/or protocols are developed, peer reviewed, and approved.	**TRL 2 Decision Criterion:** Hypothesis(es) generated. Research plans and/or protocols are developed, peer reviewed, and approved.	**TRL 2 Decision Criterion:** Hypothesis (es) generated. Research plans and/or protocols are developed, peer reviewed, and approved.	**TRL 2 Decision Criterion:** Hypothesis (es) generated. Research plans and/or protocols are developed, peer reviewed, and approved.	**TRL 2 Decision Criterion:** Medical Informatics data and knowledge representation concepts are defined, peer reviewed, and approved.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
3) Analytical and Experimental Critical Function and/or Characteristic Proof of Concept **Definition:** Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Example R&T outputs include software or hardware components that are not yet integrated or representative of final capability or system.	Basic research, data collection, and analysis begin in order to test hypotheses, explore alternative concepts, and identify and evaluate technologies supporting drug development. Initial synthesis of counter-measure candidate(s) and identification of their sites and mechanisms of action. Initial characterization of candidates in preclinical studies.	Basic research, data collection, and analysis begin in order to test hypotheses, explore alternative concepts, and identify and evaluate critical technologies and components supporting candidate biologic/ vaccine constructs research and eventual development of a candidate counter-measure. Agent challenge studies are conducted to support models based on presumed battlefield conditions. Research-scale process initiation and evaluation conducted, as are studies to identify site(s) and mechanism(s) of action, and potential correlates of protection for vaccines, initial physical/ chemical characterization of constructs.	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate component technologies. Initial tests of design concept, and evaluation of candidate(s). Study endpoints defined. Animal models (if any) are proposed. Design verification, critical component specifications and tests (if a system component, or necessary for device Test & Evaluation) developed.	Basic research, data collection, and analysis begin in order to identify and evaluate components of the problem, barriers to potential solutions, explore alternative concepts and test hypotheses. Initial work to define the approach and methodological options is performed in analytical and laboratory models. Examples include small-scale field studies and laboratory experimentation.	Separate elements of the medical information system (including Hardware and Software) components are investigated and modeled but not yet integrated or representative of final capability or system.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
4) Component and/or Breadboard Validation in Laboratory/Field Environment **Definition:** Basic technology components are integrated to establish that they will work together. This is relatively low fidelity compared to the eventual system. Examples of R&T results include integration and testing of ad hoc hardware in a laboratory/ field setting. Often the last stage for R&T (funded) activity.	Non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of candidate drugs (e.g., formulation, route(s) of administration, method of synthesis, physical/ chemical properties, metabolic fate and excretion or elimination, and dose ranging). Candidate drugs are evaluated in animal model(s) to identify and assess potential safety and toxicity problems, adverse events, and side effects. Assays to be used during non-clinical and clinical studies in evaluating candidate drugs are identified.	Laboratory research (non-GLP) to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of critical technologies for effective integration into candidate biologic/ vaccine constructs, for example, environmental milieu (pH, adjuvant, stabilizers and preservatives, buffers, etc.), route(s)/methods of administration, proposed production/purification methods, further physical-chemical characterization, metabolic fate and excretion or elimination, dose ranging, and agent challenge studies for protection. Candidate biologic/vaccine constructs are evaluated in animal model(s) to identify and assess safety and toxicity, biological effects, adverse effects, and side effects. Assays, surrogate markers, and endpoints to be used	Non-GLP laboratory research to refine hypothesis and identify relevant parametric data-required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of candidate device(s)/ systems (e.g., initial specification of device, system, and sub-systems). Candidate devices/ systems are evaluated in laboratory and/or animal models to identify and assess potential safety problems, adverse events, and side effects, Procedures and methods to be used during non-clinical and clinical studies in evaluating candidate devices/systems are identified.	Laboratory research to refine and test hypotheses and identify relevant parametric data required for assessment of candidate solution sets in a rigorous experimental design. Candidate solutions are characterized and evaluated, in laboratory models to identify and assess potential problems and verify potential utility. Procedures and methods to be used in further validation of knowledge-ware candidates are identified.	Prototypes of components are produced. System components are integrated to establish that the pieces will work together. This is relatively “low fidelity” compared to the eventual system.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
4) Component and/or Breadboard Validation in Laboratory/Field Environment (cont'd)		during non-clinical and clinical studies to evaluate and characterize candidate biologic/vaccine constructs are identified.			
	TRL 4 Decision Criterion: Proof-of-Concept demonstrated for candidate drug formulations and animal models defined.	**TRL 4 Decision Criterion:** Proof-of-concept demonstrated for candidate biologic/ vaccine constructs and animal models defined.	**TRL 4 Decision Criterion:** Proof-of-concept demonstrated for candidate devices/systems and laboratory/animal models defined. Initial device master record completed.	**TRL 4 Decision Criterion:** Proof-of-concept demonstrated for knowledge-ware candidates, experimental models, and methodologies defined.	**TRL 4 Decision Criterion:** Medical Informatics Data and knowledge representation models are initiated with representative data or knowledge from applicable domain.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
5) Component and/or Breadboard Validation in a Relevant (Operating) Environment **Definition:** Fidelity of sub-system (breadboard) representation increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so that the technology can be tested in a simulated operational environment. Examples include high fidelity laboratory/field integration of components. Rarely an R&T (funded) activity if it is a hardware system or device of any magnitude or system complexity.	Intense period of non-clinical studies involving parametric data collection and analysis in well-defined systems and a GLP/GMP environment, with pilot lot scale production and further development of selected candidate(s). Conduct GLP safety and toxicity studies in animal model systems. Identify endpoints of clinical efficacy or its surrogate. Conduct studies to evaluate the pharmaco-kinetics and pharmaco-dynamics of candidate drugs. Product Development Plan drafted.	Intense period of non-clinical and pre-clinical research studies involving parametric data collection and analysis in well-defined systems with pilot lots of candidate biologics/ vaccines produced and further development of selected candidates. Research results support proposing a potency assay, proposing a manufacturing process amenable to GMP-compliant pilot lot production, identifying and demonstrating proof-of-concept for a surrogate efficacy marker in an animal model, applicable to predicting protective immunity in humans, and demonstrating preliminary safety and efficacy against an aerosol challenge in a relevant animal model. Conduct GLP safety and toxicity studies in animal model systems. Identify endpoints of clinical efficacy or its surrogate in animal models that may be applicable to predicting protective immunity in humans. Conduct studies to evaluate	Further development of selected candidates(s). Devices compared to existing modalities and indication for use and equivalency demonstrated in model systems. Examples include devices tested through simulation in tissue or organ models, or animal models if required. All component suppliers/vendors are identified and qualified. Vendors for critical components audited for GMP compliance. Component tests, component drawings, and device master record verified. Product development Plan drafted.	Candidate knowledge-ware products (system and sub-system components) are prototyped and tested in experimental models. Proto-type components are refined, specified, and tested. Knowledge-ware technology development plan drafted.	First technical test of prototype/information system components are integrated and realistic supporting elements are employed so that the system can be tested in a simulated environment. Actual interfaces to supporting systems are specified and development begins.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
5) Component and/or Breadboard Validation in a Relevant (Operating) Environment (cont'd)		immunogenicity, as well as pharmaco-kinetics and pharmaco-dynamics when appropriate.			
	TRL 5 Decision Criterion: Dependent upon national legal requirements. In US, this is the stage at which an Investigational New Drug request should be submitted to regulatory authorities to determine if clinical trials may proceed.	**TRL 5 Decision Criterion:** A decision is made at which it is determined that sufficient data on the candidate biologic/vaccine exists to justify preparation of a technical data package which supports continued development. Dependent upon national legal requirements. In US, this is the stage at which an Investigational New Drug request should be submitted to regulatory authorities to determine if clinical trials may proceed.	**TRL 5 Decision Criterion:** Regulatory authorities have reviewed submissions of required data to determine if clinical trials may proceed.	**TRL 5 Decision Criterion:** Effectiveness of knowledge-ware candidates is demonstrated in a high fidelity laboratory or simulated operational environment. Knowledge-ware technology development plan is reviewed and approved.	**TRL 5 Decision Criterion:** Medical Informatics data and knowledge representation models are implemented as data and/or knowledge management systems and tested in a laboratory environment.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
6) System/Sub-System Model or Prototype Demonstration in a Realistic (Operating) Environment or Context **Definition:** Representative model or prototype system, which is well beyond the representation tested for TRL 5, is tested in a more realistic laboratory or simulated operational environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high fidelity laboratory/field environment or in simulated operational environment.	First clinical trials (US "Phase 1") conducted to show safety of candidate drug in a small number of human subjects under carefully controlled and intensely monitored clinical conditions. Evaluation of pharmaco-kinetic and pharmaco-dynamic data to support the design of well-controlled, scientifically valid Next-Phase (US "Phase 2") studies. Production technology demonstrated through production-scale GMP plant qualification.	National drug safety regulators must evaluate and approve first Phase clinical trials to demonstrate safety of candidate medications in a small number of subjects. Evaluation of immunogenicity and/or pharmaco-kinetics and pharmaco-dynamics data to support design of second Phase clinical trials. Surrogate efficacy models are validated.	First phase clinical trials conducted to demonstrate the safety of the candidate device in a small number of humans under carefully controlled and intensely monitored clinical conditions. Validation of the master plan for critical components and final device assembly. Production technology demonstrated through production-scale GMP plant qualifications.	System and sub-system components of the candidate systems are configured into advanced prototypes. Initial controlled trials with prototype candidates are conducted in validated model systems. Observational field studies conducted in a training environment are designed to provide statistical significance.	Advanced technical testing of prototype information systems, to include interfaces to actual supporting systems, is tested in a relevant or simulated operational environment. Output is final prototype.
	TRL 6 Decision Criterion: Data from first phase trials meet clinical safety requirements and support proceeding to the next phase of clinical studies.	**TRL 6 Decision Criterion:** Data from first phase clinical trials meet clinical safety requirements and support proceeding to the next stage of clinical trials.	**TRL 6 Decision Criterion:** Data from first phase trials meet national clinical safety requirements and support proceeding to next phase of clinical studies.	**TRL 6 Decision Criterion:** Effectiveness of the product supported by controlled studies in humans or appropriate surrogate models. These studies are designed to provide statistical significance. Validation protocols designed to test prototypes in actual operational environments with humans or validated surrogate models are approved.	**TRL 6 Decision Criterion:** Medical Informatics data and knowledge management systems are tested with target applications in a relevant or simulated operational environment. Configuration management, administration, and maintenance issues are defined.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
7) System Prototype Demonstration in an Operational Environment or Context (e.g., Exercise) **Definition:** Prototype near or at planned operational system level. Represents a major step up from TRL 6, requiring the demonstration of an actual system prototype in an operational environment, such as in a relevant platform or in a system-of-systems. Information to allow supportability assessments is obtained. Examples include extensive testing of a prototype in a test bed vehicle or use in a military exercise. Not R&T funded although R&T experts may well be involved.	Second stage clinical trials are conducted to demonstrate initial efficacy and capture further safety and toxicity data. Product activity (e.g., preliminary evidence of efficacy) is determined. Product final dose, dose range, schedule, and route of administration are established from clinical pharmaco-kinetic and pharmaco-dynamic data. Approval sought to progress to third stage of clinical trials.	Second phase safety and immunogenicity trials are conducted. Product immunogenicity and biological activity (e.g., preliminary evidence of efficacy) is determined. Product final dose, dose range, schedule, and route of administration is established from vaccine immunogenicity and biologic activity, and when necessary clinical pharmaco-kinetics and pharmaco-dynamics data. Second phase clinical trials are completed. Data is collected, presented, and discussed with regulatory agencies. Continue development is supported by regulatory agencies. Clinical endpoints and/or surrogate efficacy markers and test plans are agreed by regulatory agencies.	Second phase clinical effectiveness and safety trials are conducted with a fully integrated device prototype in an operational environment. Continuation of closely controlled studies of effectiveness and determination of short-term adverse events and risks associated with the candidate product. Functional testing of candidate devices is completed and confirmed, resulting in final selection of prototype device. Regulatory agencies have approved continued development and testing.	Small-scale validation trials conducted to test and evaluate a fully integrated prototype in actual operational environments with humans or validated surrogate models.	Prototype system is near or at planned operational system. Actual system prototype is demonstrated in an operational environment with end-users.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
7) System Prototype Demonstration in an Operational Environment or Context (e.g., Exercise) (cont'd)	**TRL 7 Decision Criterion:** Second Phase clinical trials completed. Data collected, presented, and discussed with regulatory agencies. Regulatory agencies agree to continued development. Clinical endpoints and or surrogate efficacy markers and test plans are agreed. Third phase clinical study plan is approved.	**TRL 7 Decision Criterion:** Next phase clinical study plan or surrogate test plan has been approved.	**TRL 7 Decision Criterion:** Second Phase clinical effectiveness and safety trials are completed. Final product design is validated, and final prototypes and/or initial commercial scale devices are produced. Data is collected, presented, and discussed with regulatory agencies. Agencies support continued development. Clinical endpoints and test plans agreed to by regulatory agencies. Next Phase clinical study plan is approved.	**TRL 7 Decision Criterion:** Small-scale validation trials successfully completed. Data has been collected and validate the fully integrated prototypes and support proceeding to full-scale validation trials.	**TRL 7 Decision Criterion:** Medical informatics data and knowledge management systems are operationally integrated and tested with target applications in an operational environment.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
8) Actual System Completed and Qualified through Test and Demonstration **Definition:** Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of Demonstration. Examples include test and evaluation of the system in its intended environment to determine if it meets design specifications, including those relating to supportability.	Implementation of expanded controlled and uncontrolled Phase 3 clinical trials or surrogate tests to gather information relative to the safety and effectiveness of the candidate drug. Trials are conducted to evaluate the overall risk-benefit of administering the candidate product, and to provide an adequate basis for drug labeling. Process validation completed and followed by lot consistency/reproducibility studies. Stability studies initiated. New Drug Application submitted to appropriate national or international regulatory authorities.	Implementation of expanded controlled and uncontrolled Phase 3 clinical trials or surrogate tests to gather information relative to the safety and effectiveness of the candidate biologic/ vaccine. Trials are conducted to evaluate the overall risk-benefit of administering the candidate product, and to provide an adequate basis for product labeling. Process validation completed and followed by lot consistency/ reproducibility studies. Stability studies initiated.	Implementation of expanded controlled and uncontrolled Phase 3 trials to gather information relative to the safety and effectiveness of the device. Trials are conducted to evaluate the overall risk-benefit of using the device, and to provide an adequate basis for product labeling. Process validation completed and followed by lot consistency/ reproducibility studies.	Full-scale validation and beta-testing trials conducted to test and evaluate a fully integrated prototype in as close to the intended operational environment as possible (e.g., ATD, ACTD, or EPOW Experiment). Refinement of product to address any deficiencies revealed in full-scale validation studies and beta-test feedback from user. Product undergoes independent, external review.	Technical testing of Final Product. System has been proven to work in its final form and under expected conditions.
	TRL 8 Decision Criterion: Approval of New Drug Application by national or international regulatory authorities.	**TRL 8 Decision Criterion:** Approval for production given by national or international regulatory authorities.	**TRL 8 Decision Criterion:** Approval of the device by national or international regulatory authorities.	**TRL 8 Decision Criterion:** External review approval equivalent to ANSI or ANSI-like standard is obtained.	**TRL 8 Decision Criterion:** Developmental test and evaluation of the system in its intended environment demonstrate it meets design specifications. Fully integrated and operational Medical Informatics Data and knowledge management systems are validated in several operational environments.

NATO Technology Readiness Level and Definition	Pharmaceutical (Drug)	Pharmaceutical (Biologics/Vaccines)	Medical Devices	Medical Knowledge-Ware	Medical Information Technology and Medical Informatics
9) Actual System Operationally Proven through Successful Mission Operations **Definition:** Application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation and reliability trials. Examples include using the final system under operational mission conditions.	Post-Marketing studies (clinical or non-clinical) may be required by national or international regulatory authorities. Post-Marketing Surveillance.	Post-Marketing studies (clinical or non-clinical) may be required by national or international regulatory authorities. Post-Marketing Surveillance.	Post-Marketing studies (clinical or non-clinical) may be required by national or international regulatory authorities. Post-Marketing Surveillance.	Final product and all documentation completed and provided to end-user community for implementation. Examples include integration of information into doctrine, transfer of information to project manager for use in system design.	Operational testing of the product. The system is in its final form and under mission conditions, such as those encountered in operational test and evaluation. Medical informatics knowledge maintenance and verification of data integrity are ongoing requirements for transportation, handling, storage, etc.
	TRL 9 Decision Criterion: None – continue surveillance.	**TRL 9 Decision Criterion:** None – continue surveillance.	**TRL 9 Decision Criterion:** None – continue surveillance.	**TRL 9 Decision Criterion:** Final acceptance of knowledge-ware design by end-user.	**TRL 9 Decision Criterion:** Product successfully used during military mission as part of operational testing and evaluation. Logistical demonstration successfully conducted.

Produced by RTG-130. Derived in large part from work done by NATO Undersea Research Center, United States National Aeronautics and Space Administration, and United States Army Medical Research and Materiel Command.

Definitions – Only applicable to Drug, Biological, and Vaccine Development:

- First Phase Studies – Small dose studies using 10 – 50 healthy volunteers to monitor: Adverse Events (AE); toxicology; and pharmaco-kinetics. The goal is to determine safety and dose ranges for future trials.
- Second Phase Studies – Larger studies using variable dosages on 100 – 200 target population patients, to monitor: effect(s) on disease; dosage; safety/AE/side effects; and pharmaco-kinetics. The goal is to determine appropriate dosages and frequency of administration, and whether to proceed with the development.
- Third Phase Studies – Still larger studies at many sites with a large and diverse patient population to monitor the effects on many types of diseases and safety. Placebo comparison will be used, as will comparison to other products on the market. The goal is to determine appropriate clinical usage guidelines and labeling.

NOTE: If a newly evaluated device or system seems to fall into two or more of the above categories of product, e.g., a medical device which is an integral part of a medical information system. It should be evaluated in accordance with the rules for both categories, and will be considered to be at the lower of the two TRLs so determined.

Annex B – NATO MEDICAL PRODUCT REGULATORY CONSIDERATIONS AND CHECKLIST

In most cases procurement of medical devices or products for NATO use will be the responsibility, as it has been in the past, of a participating member nation for its constituent forces. In these cases, regulatory concerns are the responsibility of the nation rendering medical care as prescribed by its countries laws and regulatory bodies. In the future, NATO may seek to procure medical devices or products for use by multiple member nations. In these instances, the following discussion may guide a team planning to test and/or procure medical products to recognize potential regulatory considerations.

B.1 MEDICAL PRODUCT REGULATORY OVERSIGHT

Procurements covered by this document will generally only include approved EU (CE mark) or FDA medical products. It is conceivable that approvals by other regulatory bodies from host nations could be considered, but these products would need to be analyzed in conjunction with CE, FDA, or alternative consensus standards to be developed. Any such decisions should also address any applicable NATO policy. Since forces from member nations serve under NATO command, NATO member nations should establish a formal policy that medical products procured and utilized within the framework of any NATO program are considered consistent with the medical product regulatory expectations and standards of care of the member nations.

In other words, a policy should be established that allow NATO medics from the US to use CE mark medical products on NATO or Partnership for Peace soldiers, sailors, or airman and all other categories of patients if the medic is serving on a NATO mission. Likewise, NATO medics from other member or partner nations could use FDA approved medical products on soldiers, sailors, or airman and all other categories of patients from NATO or Partnership for Peace countries.

B.2 STRATEGY FOR PROCUREMENT

B.2.1 NATO Medical Procurement

NATO Medical Procurement will:

- Apply unified standards of acceptable quality, safety and efficacy.
- Comprehensively evaluate the quality, safety and efficacy of medical products, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing sites, along with military specific specifications.
- Establish points of contact with national regulatory authorities to assure that the medical products being procured meet appropriate compliance expectations.
- Ensure testing to meet NATO military specifications will be accomplished by NATO or entities that can demonstrate the needed capabilities and security.

B.2.2 Description of Needs

B.2.2.1 Defining the Specifications

Defining the specifications for medical products hinges on clearly articulating the intended use and indications for use. For practical and regulatory expediency, only medical products which have been approved by

appropriate national or international medical product regulatory authority(ies) shall be procured by NATO. NATO (NAMSA) will determine that medical products are registered, i.e., have a Marketing Authorization, or other such document from an appropriate medical product regulatory authority (ies) prior to contracting to purchase such medical equipment. Further, NAMSA should ensure that, in the case of medical systems (e.g., telemedicine systems, evacuation systems, or field hospitals), they have appropriately been tested by ACT or another appropriate NATO body to demonstrate that they can be successfully integrated into and/or be used within the NATO multi-national field operational environment.

B.2.2.2 Emergency Use of Approved Medical Products

Emergency use of approved medical products for non-approved intended use and indications for use should meet the regulatory expectations of the appropriate nation(s) using the medical product or medical systems.

B.2.2.3 Forecasting

Forecasting of Needs – For planning purposes, manufacturers require long-term forecasts for products and quantities, preferably for six to 24 months, which take account of the following: safety stocks, shelf-life, cold-storage and cold transportation considerations, as needed, and warehousing capacity and in-country logistics.

B.2.2.4 Order Quantity and Ordering Interval

It is important to establish the quantity required per product per period, and ideally plan orders in advance.

B.2.2.5 Delivery Lead-Time

It is vital to establish when the products are required to arrive in-country, and integrate this in the procurement plan. Lead times can be up substantial for some products.

B.2.2.6 Quality Assurance of Products

NATO may establish specifications that address military expectations for the performance of medical products, such as field ruggedness, ability to interface with existing medical equipment; ensure interference with other equipment/medical devices does not occur, etc., and other military specific needs:

- **Pre-Qualification Program** – In close cooperation with national regulatory agencies and partner organizations, a NATO Prequalification Program may be established ad hoc that seeks interoperable, quality medical products, including drugs, devices, biologics, and other medical products available for NATO forces that are sensitive to the regulatory requirements of the component NATO forces and the proposed sites of medical product use. This may be optimally achieved through its evaluation and inspection activities, and by building multi-national capacity for sustainable manufacturing and monitoring of quality medical products.

B.2.2.7 Packaging

Packaging of procured medical products – The specific packaging materials will be included in the description of needs, and shall take into account the environments where the medical product(s) will be utilized. Such considerations shall include how the environment could affect the stability, safety, efficacy, performance, and shelf life of the medical products in their deployed situation. Additionally, specific product markings as

may be required by various STANAGS will be specified in the description of needs. Testers should identify if packaging meets identified requirements:

- **Pre-Shipment Inspection:** The need for pre-shipment inspections will be articulated in the description of needs.
- **Consignee:** Full consignee details, including a contact person, must be provided.

B.3 MEDICAL DEVICES (INCLUDING SYSTEMS) AND KITS

To support its program goals and policies, NATO, through NAMSA or through the member nations, may procure medical devices that meet specific program requirements and can be supplied at competitive rates. The role of providing medical devices is essential and irreplaceable in the delivery of healthcare.

B.3.1 Medical Devices and Kits

Medical devices and kits cover five products groups:

- Medical equipment (including systems);
- Medical renewable;
- Medical/hygiene sets, kits, and outfits;
- Laboratory supplies; and
- Diagnostic test kits.

Each of these product groups is divided into several sub-groups which lead to individual items.

B.4 DEFINITIONS OF MEDICAL DEVICES

B.4.1 Medical Devices

Medical devices are any instrument, apparatus, implement, machine, appliance, implant, *in vitro* regent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury.
- Investigation, replacement, modification, or support of the anatomy or of a physiological process.
- Supporting or sustaining life.
- Control of conception.
- Disinfecting of medical devices.
- Providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

An accessory is not necessarily considered to be a medical device. However, when an accessory is intended specifically by its manufacturer to be used together with the "parent" medical device to enable the medical device to achieve its intended purpose, it should be subject to the same procedures that apply to medical devices. For further information see Global Harmonization Task Force (GHTF) guidance documents[1].

The definition of a device for *in vitro* examination includes, for example, reagents, calibrator, samples collection devices, control materials, and related instruments or apparatus. The information provided such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, reagents and the like may be covered by separate regulations.

Products which are considered to be medical in some jurisdictions but for which there is not yet an international harmonized approach, are not covered within this document, e.g.,:

- Aids for disabled/handicapped people.
- Devices for the treatment/diagnosis of diseases and injuries in animals.
- Spare parts for medical devices.
- Devices incorporating animal and human tissues which may meet the requirements of the above definitions but which may be subject to different controls.

B.5 REGULATION

If a decision is made to procure a medical product or device that is not FDA or EC approved, then emerging Global Harmonization Task Force (GHTF) guidelines may provide assistance. Government authorities of the country in which a product is manufactured or imported usually enforce regulations. However, many countries do not yet have regulations for medical devices, or these regulations are sparse or fragmentary. Although it is encouraging that some countries are in the process of establishing such regulations, a proliferation of different national regulations could hinder access to technology and should be avoided.

The GHTF[2] is a voluntary group of representatives from national medical devices regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of five founding members grouped into three geographic areas. The five founding members are the European Union, Japan, Australia, Canada and the United States of America. The three geographic areas are Europe, Asia-Pacific and North America, each of which actively regulates medical devices using their own unique regulatory framework.

The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation and facilitating international trade. This is primarily accomplished through the publication and dissemination of harmonized guidance documents on basic regulatory practices.

The GHTF also serves as an information exchange forum through which countries developing medical device regulatory systems can benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members.

[1] GHTF doc. SGI/N029R11– date: February 25, 2002.

[2] http://www.ghtf.org.

B.5.1 Standards and Regulatory Requirements[3]

The means to ensure the safety and performance of the medical devices include standards and national regulations. In general, **standards are voluntary** while **regulations are mandatory**. However **regulations can make certain standards mandatory**. In addition, NATIONAL or MULTI-NATIONAL purchasers may also have their own specifications that a product must fulfill.

B.5.1.1 Product Standards

Product standards describe characteristics and performances of the product.

B.5.1.2 Quality System Standards

Quality system standards provide the essential elements that a manufacturer should have in place to ensure that the quality of products manufactured is consistent.

B.5.1.3 Types of Standards

- Product standards;
- Procurement specifications; and
- Quality system standards.

B.5.1.4 Elements of Regulatory Requirements

- Conformity with product standards;
- Consistency in product quality;
- Packaging and labelling; and
- Marketing clearance.

B.5.2 Proposed Management of Medical Device Procurement

B.5.2.1 NATO Oversight of Medical Procurement Programs

NATO needs to designate an appropriate NATO entity which is responsible for identifying the most appropriate medical devices and ensuring that NATO offices and external customers can purchase quality medical devices at an affordable price. Normally, such decisions would follow systematic T&E or MTD studies as per Chapters 4 and 5. The NTO, responsible for system testing in the context of NATO operations and doctrine would not normally carry out this type of pure logistic analysis and function, which could most appropriately be carried out by the Medical Branch at the NATO Maintenance and Supply Agency (NAMSA), after the requirements are doctrinally evaluated by ACT.

[3] **Note**: There are different types of standards (e.g.: private, public, organizational, regional, national and international standards). As health care products, medical devices normally follow international standards. The GHTF aims at harmonizing regulatory requirements and practices based upon essential principles and common criteria. At this time, conformity assessment requirements and other regulatory controls assigned to each class of devices by different regulatory authorities have yet to be harmonized and many vary.

B.5.2.2 NAMSA Procurement Role

As NATO develops its medical procurement role, NAMSA or some other designated logistic agency can provide technical support to national or organizational procurers, which support could include:

- Assessing and analyzing NATO needs in the context of health systems, policy and regulation, and the supply system.
- Assessing health structures regarding supply planning for various types of medical needs.
- Defining customer needs for products in the context of the environment of utilization, policy and legislation, international norms and regulation and promotion of protocols for the evaluation of product use, replenishment, maintenance and quality.
- Assisting appropriate NATO agencies to perform appropriate Testing and Evaluation of the use of medical devices and systems in the multi-national and field setting, as recommended in other parts of this document.
- Assessing and analyzing sourcing options for NATO standard and non-standard products.
- Assessing the supply chain and identifying needs to optimize the supply function.
- Identifying priorities/constraints in coordination with different partners involved in implementing a project in order to address customer needs effectively.
- Providing support for training.

B.5.2.3 Proposed NATO Procurement Criteria for Medical Devices and Kits

- Purchase only from appropriately licensed entities.
- Purchase only from manufacturers with a proven record of competence, knowledge and experience.
- Purchase only from suppliers of medical devices certified in accordance with ISO 9001/EN46001 or ISO 9002/EN 46002.
- Purchase only from manufacturers who conform to Good Manufacturing Practices (GMP) and quality management system / design control guidelines and which are regularly inspected by the appropriate national regulatory authorities.
- Purchase only from those vendor or producers that have good manufacturing practice / quality management system / design control inspections performed by NATO's own qualified GMP inspector, by a Foreign Regulatory GMP Inspectorate or by independent consultants with a long experience in this area. Suppliers are normally inspected every 2 to 4 years, depending on the regulatory environment in the country of origin.
- A Marketing Authorization for the product in the market of the country of origin is generally required for medical devices. Products may also meet the essential requirements described in the EEC Directive: Council Directive 93/42/EEC of 14/06/1993 (CE Marking).
- An independent laboratory analysis of randomly picked samples of the products delivered to NATO may be conducted.
- NATO may inspect products shipped directly from suppliers using NATO or a designated representative when applicable.

- Testing to meet NATO specific military specifications should be accomplished by NATO or entities that can demonstrate the needed capabilities and security.
- The suitability of packing and labeling should be subject to both technical and quality checks before purchasing.
- The minimum shelf-life remaining of medical products supplied to NATO should be 24 months or as indicated in the description of need.
- A recall system is in place for quality issues.
- Establish technical, quality assurance, and procurement processes to ensure that both suppliers and the medical devices they offer are in accordance with NATO's expectations.

B.5.2.4 Technical and Quality Assurance Processes

Technical and quality assurance processes for medical devices cover:

- Supplier quality assurance system: good manufacturing and distribution practice;
- Supplier inspection of manufacturing site;
- Product conformity to international standards;
- Product specifications;
- Product documentation;
- Product shelf life (when applicable);
- Certificate of sterilization (when applicable);
- Product packaging and labelling; and
- Product marketing authorizations.

B.5.2.5 Specific Requirements for Equipment

Specific requirements for equipment include:

- Product conformity with final destination of goods;
- Supplier services: installation, training on site; and
- Supplier warranty and after-sale service.

B.5.3 Drugs/Pharmaceuticals, Biologics, Vaccines, Combination Products, and Medical Foods

B.5.3.1 Definitions

- **Drugs/Pharmaceuticals:** Drugs are defined by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and articles (other than food) intended to affect the structure or any function of the body of man or other animals".
- **Biologics and Vaccines:** A biological product is defined as "a virus, therapeutic serum, toxin, anti-toxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, applicable to the

prevention, treatment or cure of a disease or condition of human beings". Biological products include viruses, therapeutic sera, toxins and anti-toxins, vaccines, blood, blood components or derivatives, allergenic products, and any analogous products, used for treating disease.

- **Combination Product:** The term combination product includes:
  1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.
  2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products.
  3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose.
- **Medical Foods:** A medical food is "a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation". Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision and intended for the specific dietary management of a disease or condition. The term "medical foods" does not pertain to all foods fed to sick patients. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for the patient who is seriously ill or who requires the product as a major treatment modality. In general, to be considered a medical food, a product must, at a minimum, meet the following criteria: the product must be a food for oral or tube feeding; the product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be intended to be used under medical supervision.

B.5.3.2 NATO (and NATO Nations') Procurement Criteria for Medical Products (Pharmaceuticals, Biologics, Vaccines and Medical Foods)

The quality of medical products is a major concern for NATO. As a result the following policies are recommended:

- Purchase only from appropriately licensed Entities.
- Purchase only from manufacturers with a proven record of competence, knowledge and experience.
- Ensure manufacturers conform to Good Manufacturing Practices (GMP) guidelines and be regularly inspected by national regulatory authorities. Good Manufacturing Practice inspections are performed by a NATO qualified or designated GMP inspector, by a Foreign Regulatory GMP Inspectorate or by independent consultants with a long experience in this area. Suppliers are normally inspected every 2 to 4 years, depending on the regulatory environment in the country of origin.
- A Marketing Authorization for the product in the market of the country of origin is generally required for medical products (Pharmaceuticals, Biologics, Vaccines and Medical Foods).

- A Certificate of Analysis can accompany all medical products (Pharmaceuticals, Biologics, Vaccines and Medical Foods) for each batch supplied as appropriate.
- An independent laboratory analysis of randomly picked samples of the products delivered to NATO may be conducted.
- Testing to meet NATO specific military specifications will be accomplished by NATO or entities that can demonstrate the needed capabilities and security.
- The suitability of packing and labeling is subject to both technical and quality checks before purchasing.
- The minimum shelf-life remaining of medical products (Pharmaceuticals, Biologics, Vaccines and Medical Foods) supplied to NATO is 24 months or as indicated in the description of need.
- A recall system is in place for quality issues.

B.5.3.3 Pharmaceuticals, Biologics, Vaccines and Medical Foods Procured by NATO

Pharmaceuticals, biologics, vaccines and medical foods procured by NATO must be manufactured and conform to the latest edition of British, United States, European or International Pharmacopoeia, if such a monograph exists. For non-pharmacopoeia products, the finished product specifications from the description of needs are used. Raw materials used in manufacturing must be of good quality and from approved sources only and conform to the standards in the latest edition of British Pharmacopoeia, United States Pharmacopoeia, European Pharmacopoeia or International Pharmacopoeia, whenever applicable. Pharmaceutical containers must conform to the latest pharmacopoeia, whenever applicable. Packaging should be suitable for delivery and use in countries with adverse climatic and storage conditions and consistent with military specifications and be suitable for shipment, storage and use worldwide at temperatures and humidity specified in the description of needs. The containers should normally be tamper-proof and the size proportional to the contents with the addition of appropriate padding to prevent damage to the product during shipment.

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Annex C – REVIEWING CAPABILITIES BASED REQUIREMENTS DOCUMENTS

C.1 TESTER DOCUMENT REVIEW RESPONSIBILITIES

In developing a test plan, the plan developer needs to ensure that the following items are addressed:

- **Capability Discussion –** Review this section to make sure it is an overarching discussion that encompasses Key Performance Parameters (KPP), thresholds and objectives.
- **Concept of Operations Summary –** Review this section to make sure the concepts discussed are directly tied to requirements.
- **Threat Summary** – Make sure that any discussion regarding *Threats to be Countered* addresses threats to the proposed system that the system is expected to counter.
- **Environmental Impact** – Make sure that member nation guidance regarding environmental concerns to include hazardous conditions is adhered to.
- **System Capabilities Required for the Current Increment –** Increases requirement by adding KSAs (key system attributes):
  - If this section contains an effectiveness requirement that includes reliability it should be commented on. T&E results can be compromised by allowing a low reliability to be compensated for by high effectiveness. This can cause problems down the road leading to additional testing.
  - Review this section making sure only a minimum number of requirements are KPP.
  - Attributes should be validated for testability.
  - Know the difference between KPP/KSA (see definitions in Glossary).
  - Performance attributes apply only to a single increment so ensure testing can be accomplished on current planned increment.
- **Schedule and Initial Operational Capability (IOC)/Full Operational Capability (FOC) Definitions –** Make sure IOT&E/FOT&E is discussed here if appropriate.
- ***Other System Attributes*** – Check this section for additional testability of system attributes.

Annex D – OPERATIONAL TEST: TEST CONCEPT (OT TC)

(To be used as an example of a Usable Plan –
Not to be Considered Directive in Nature)

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Annex G – TAP FOR RTG-130

Technical Activity Proposal

ACTIVITY	RTG	DEVELOPMENT OF AN ASSESSMENT METHODOLOGY FOR DEMONSTRATING USABILITY, TECHNICAL MATURITY, AND OPERATIONAL BENEFITS OF ADVANCED MEDICAL TECHNOLOGY												TBA
Activity Ref. Number	HFM-130/RTG													01/2005
PRINCIPAL MILITARY REQUIREMENTS		1	2	3	4					NU				12/2007
MILITARY FUNCTIONS		1	4	9	10	11	12	13	14					
PANEL AND COORDINATION		HFM								ACO/ACT/ COMEDS				MIMS WG/ TMED PANEL
LOCATION AND DATES		BI-ANNUALLY												P-I
PUBLICATION DATA		TR/STANAG/ALLIED PUBLICATION						12/2007				200		UU
KEYWORDS	ADVANCED MEDICAL TECHNOLOGY	TEST				ASSESSMENT				TELEMEDICINE				
HUMAN FACTORS		TEST PROCEDURES												

I. BACKGROUND AND JUSTIFICATION

Advanced medical technologies (often called telemedicine) are widely seen as having potential benefit to patients, clinicians, and commanders in multi-national operations in a field setting. Adoption of any particular technology or telemedicine modality for Alliance support is hindered by the lack of any standardized NATO assessment mechanism which can evaluate and assess new medical technologies for technical maturity, usability (in the classic human factors sense), and benefits to the patient, the clinician, and the operational commander. Development of such an evaluation mechanism could lead to increased deployment of such advanced medical technologies, as well as increased interoperability.

II. OBJECTIVE(S)

- To assemble a database of tried/proposed evaluation methodologies for new advanced medical technology;
- To use the best of these to produce a single standardized NATO test and evaluation methodology for this type of equipment; to test the new methodology during a Cooperative Technology Demonstration (CDT) – in conjunction with a NATO exercise;
- To modify the proposed methodology as needed; and
- To publish the standardized methodology as a NATO standardization document.

III. TOPICS TO BE COVERED

- Historical review of advanced medical technology test and evaluation procedures;
- Operational issues;
- Functional issues;
- Human factors usability issues;
- NATO requirements;
- Operational testing; and
- Standardization.

IV. DELIVERABLE AND/OR END PRODUCT

- Database of current/proposed test and evaluation procedures;
- Standardized NATO test and evaluation procedure; and
- Standardization document.

V. TECHNICAL TEAM LEADER AND LEAD NATION

Dr. David Lam (USA).

VI. NATIONS WILLING TO PARTICIPATE

BUL, CAN, CZE, FIN, GBR, ITA, NOR, USA.

VII. NATIONAL AND/OR NATO RESOURCES NEEDED

Some nations already have national programs to develop and test such advanced medical technology. The Task Group (TG) members need to obtain permission for the release of national test protocols and experience to the TG. During the CDT phase, nations will need to be willing to loan such medical devices/equipment for field-testing in accordance with the developed test methodology. Each nation will be responsible for its own travel funding. ACO and ACT Medical Advisors will need to provide input to the TG on operational requirements for such advanced medical technology, as well as on development of the scenario for the CDT. The CDT will have to be invited by ACO/ACT to integrate the CDT into a NATO field exercise, and the Exercise DISTAFF will need to support such integration logistically and operationally.

VIII. RTA RESOURCES NEEDED

- Normal support for RTO Task Group.
- Hosting of first meeting at RTA HQ.

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Telemedicine
Test and evaluation

14. Abstract

Advanced medical technologies are increasingly available for operational use. These technologies can potentially be of benefit as a medical force multiplier. However, adoption of any particular technology for Alliance support is hindered by lack of a NATO mechanism to assess new medical technologies for maturity, usability, and benefits to the patients, clinicians, and operational commanders. The availability of a standardized assessment/evaluation methodology could significantly assist in the decision as to whether to field this technology in the multi-national environment, and could lead to increased deployment of such capabilities. RTG-130 has examined the mechanisms currently in use by various nations to test the suitability of such devices, and has examined the literature on Health Technology Assessment and Medical Equipment Testing. We have also attempted to determine how such testing could potentially be inserted into the current exercise and material-testing programs of NATO. A schema for using the concept of Technology Readiness Levels (TRLs) in the evaluation of biomedical developments has been developed and recommended for formal NATO adoption. Proposed test and/or demonstration procedures/processes for evaluation of future systems for use within the NATO multi-national environment have been developed, which recommend assignment of this task to the ACT Medical Branch.

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