Test and Evaluation (T&E) of Biological Detection, Identification and Monitoring (BioDIM) Equipment

Results of the EDA T&E BioDIM Phase 1 Project: "Exchange of information and scoping study"

This short communication summarizes the results of the European Defence Agency (EDA) Category B T&E BioDIM Phase 1 "Exchange of information and scoping study concerning test and evaluation (T&E) of biological detection, identification and monitoring (BioDIM) equipment" Project. The overall aim of the project was to define requirements and criteria for T&E of BioDIM equipment as defined in the EDA Integrated Biological Defence System Architecture (IBDSA) report. By working out a generic T&E framework, the T&E BioDIM project contributed to define and highlight several important aspects of T&E processes for BioDIM equipment. Minimum requirements, general recommendations and guidelines were described whenever appropriate, including suggestions on how to approach conceptual and procedural T&E coordination, harmonization and standardization. In the final report of the T&E BioDIM Phase 1 project, the following themes were addressed:

- "Introduction" describing the background of the work and identified knowledge gaps
- "Concepts for T&E of BioDIM equipment"
- "Selection of biological simulants for T&E of BioDIM equipment"
- "T&E criteria for biological point detectors and air samplers"
- "T&E criteria for biological identification equipment"
- "Conclusions"

An important gap identified by several national and international defense organizations is the lack of interagency and international coordination and harmonization regarding T&E of BioDIM equipment. This makes it difficult to compare and exchange T&E results both within and between European countries as well as Allied nations in the North Atlantic Treaty Organization (NATO). This lack of coordination and harmonization causes duplication of effort and reduces the cost-effectiveness of both national and international military and civilian T&E efforts, e.g. by limiting the burden-sharing and cost-reduction potential that could have been realized.

Harmonization of concepts and procedures for T&E of BioDIM equipment will be needed to allow for reliable comparison and exchange of T&E results between different laboratories and nations. The T&E BioDIM project proposed a concept for procedural T&E harmonization as illustrated in Figure 1. Another crucial factor in enabling exchange and reliable comparisons of T&E results will be having appropriate control mechanisms in place to ensure that the T&E concepts and procedures, including biological test materials and test facilities are properly applied (i.e. quality assurance).

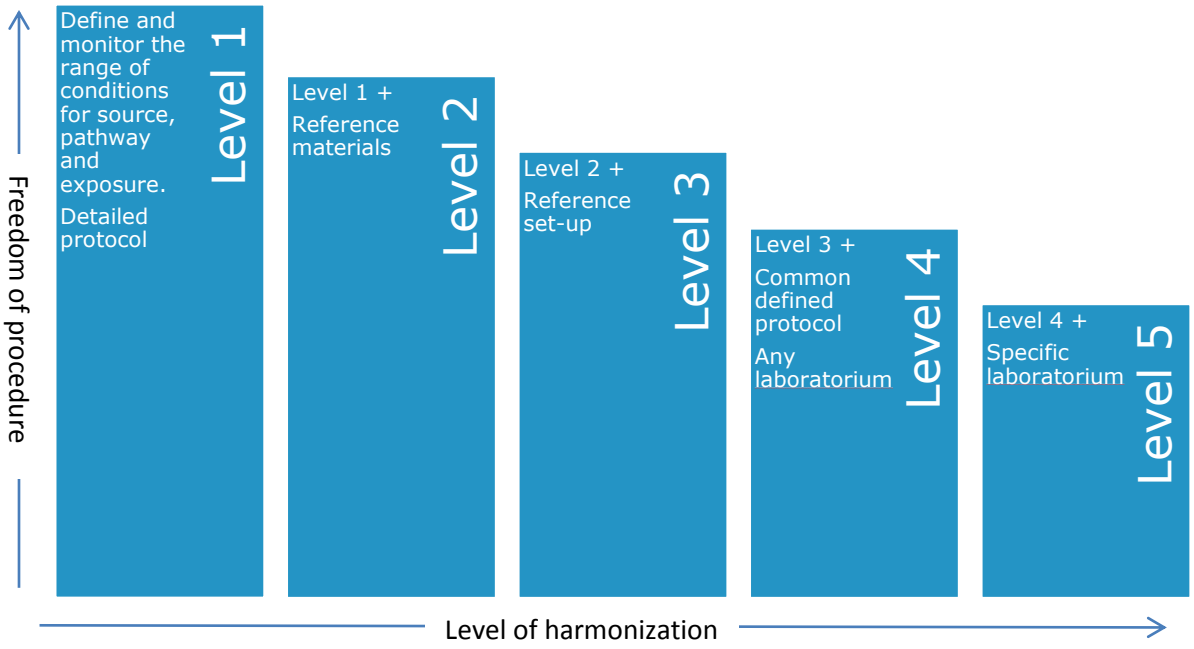

Figure 1. *Five levels of harmonization were proposed as part of the T&E BioDIM project. The figure shows the freedom of procedure as a function of the level of harmonization. The proposed harmonization levels are intended mainly to be used as guidelines in the ongoing process of defining and reaching a community consensus concerning the conceptual and procedural framework for coordinated and harmonized T&E of BioDIM equipment in Europe.*

One important step in allowing for more reliable comparisons of T&E results is to define a relevant set of biological simulants. The T&E BioDIM project defined a core set of simulant selection criteria, including practical and legal constraints, which may be used to support future selection of standardized biological simulants that will represent the entire spectrum of relevant biological threat agents, including bacterial spores, vegetative bacterial cells, viruses and toxins. General recommendations concerning the selection of biological simulants for T&E of BioDIM equipment were also provided. The selection criteria for biological simulants may broadly be separated into two classes based on whether they can be related to:

- The simulant's ability to serve as a realistic surrogate for one or several classes of biological threat agents, e.g. due to similarity in physical and biological properties.
- The practical use of the simulant for T&E purposes, e.g. ease and cost of production, health and safety considerations, regulatory and legal aspects, and the availability of appropriate techniques for aerosol generation and reference measurement.

The focus of the T&E BioDIM project has been on establishing a conceptual and procedural T&E framework for biological point detectors, air samplers and integrated BioDIM equipment (e.g. automated detection, air sampling and identification systems), with special emphasis on design, planning and execution of T&E processes involving aerosol challenges. The T&E process for BioDIM equipment can be described as an ensemble of test events where the system under test, e.g. a detector, air sampler or integrated BioDIM system, is exposed to a range of controlled or at least monitored aerosol challenges in order to measure the performance of the system against a paradigm (e.g. functional requirements, acceptance criteria or vendor-claimed specifications). Aerosol challenges used for T&E of BioDIM equipment will typically be produced from wet or dry test material containing a biological simulant or interferent(s).

In order to be able to compare T&E results from different test facilities (inter-laboratory comparisons) or different test events within the same facility (intra-laboratory comparisons), a number of parameters and conditions must be defined, controlled, monitored and documented as part of the T&E process. As illustrated in Figure 2, T&E processes for BioDIM equipment can be divided into three main steps: i) Design and planning *"Test design"*, ii) Test execution "*Test event"*, and iii) Data analysis and evaluation "*Evaluation"*. The test event can similarly be described as a process which consists of three distinct steps or processes, namely "source, pathway and exposure".

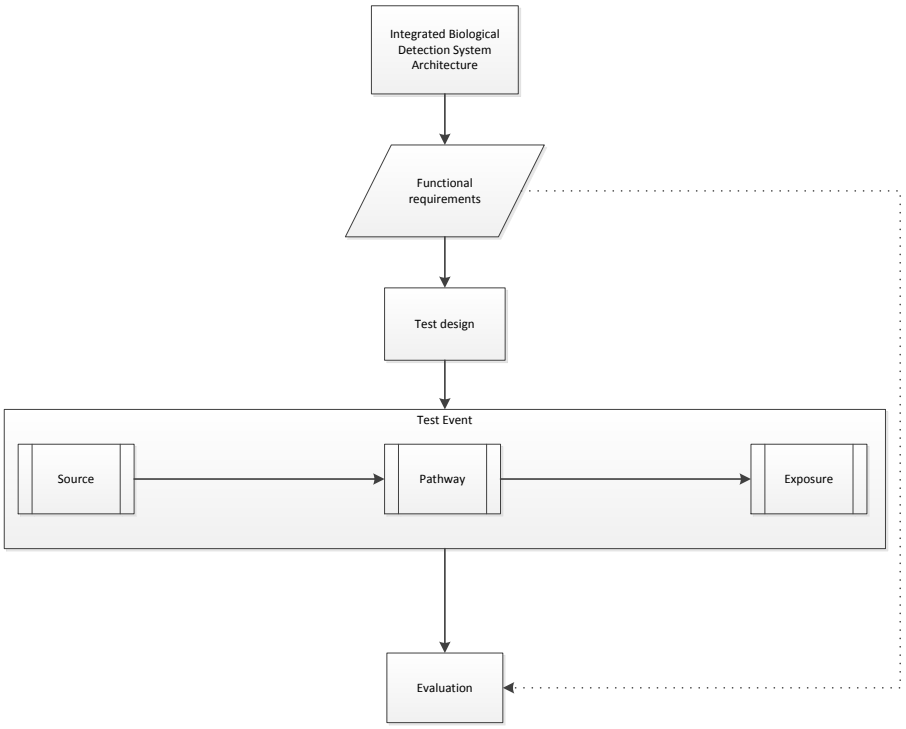

Figure 2. *Schematic visualization showing the generic BioDIM T&E process map as proposed by the T&E BioDIM project.*

The main functional parameters, or alternatively functional criteria, that should be used to describe and assess the functional performance of BioDIM equipment are; sensitivity, detection probability, false alarm rate and response time. These four parameters are inherently interrelated and it is therefore meaningless to express them separately. The performance parameters can be captured and visualized quantitatively using Receiver Operating Characteristics (ROC) curves. Since the functional performance of most or all current near-real time biological point detectors at least to some degree will depend on their operating environment, it is similarly meaningless to express their functional performance parameters without a specified environmental context.

T&E criteria for biological identification (bioidentification) technologies were by the T&E BioDIM Phase 1 project only addressed in the context of aerosol T&E and bioidentification equipment operating as part of an integrated BioDIM system. In addition to the generic considerations associated with aerosol T&E of BioDIM equipment, a T&E process for bioidentification equipment will also have to take into account the discrimination of biological organisms at the species and sometimes even at the strain level. For non-aerosol T&E of bioidentification equipment, existing T&E procedures for bioidentification equipment intended for non-aerosol samples (e.g. food, soil, water or clinical samples) should be applied instead of developing new procedures.

Having access to reliable and cost-effective T&E capabilities for BioDIM equipment may be considered as an essential prerequisite for resource-effective biodefense both within national and international defence organizations. Reliable T&E processes will be fundamental to ensure that the Armed Forces of European countries have access to BioDIM capabilities that can be relied upon to protect our soldiers, their missions and the society in the event of a natural, accidental or intentional biological incident. Although the T&E BioDIM Phase 1 project can be considered as a modest initiative in terms of size, the outcome of the work may nonetheless have a major impact on the way T&E of BioDIM equipment is performed, and by doing so the T&E BioDIM initiative including the results of the Phase 1 project and its foreseen Phase 2 continuation may contribute to speed up the ongoing and urgently needed process of closing important biodefense capability gaps in Europe.