Defence Research and Development Canada
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Toward the Development of a Canadian Less Lethal Weapon Approval Process:

A Study of Contemporary Process Models

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Technical Memorandum
DRDC CSS TM 2011-17
October 2011

Canada

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This work was done for the Conducted Energy Weapons Strategic Initiative (CEWSI), project number 32bj, a project funded by the Canadian Police Research Centre (CPRC) and managed by Defence Research and Development Canada (DRDC) under the Centre for Security Science (CSS).

Abstract

One of the objectives of the Conducted Energy Weapons Strategic Initiative (CEWSI) project is to develop a Canadian approval process that could be applied to emerging less lethal technologies. A contract was let with Alcea Technologies to survey a variety of approval processes with the objective of identifying common elements that could be applied to the Canadian less lethal weapons approval process.

The contractor identified the stakeholders, roles and responsibilities, governance framework, high level processes and supporting documentation for the Less Lethal Weapons Approval Process used by the United States and the United Kingdom as well as for the following Canadian approval processes: Medical Devices, Telecommunications Devices, Unmanned Aerial Vehicles, CSA approval and the use of the Laser-Dazzler by the Canadian Forces in Afghanistan.

This report presents the findings of the contractor's work, identifies the common elements among the processes and recommends building blocks that should be included in a Canadian less lethal weapons approval process.

Résumé

L'un des objectifs de l'Initiative stratégique sur les armes à impulsions (ISAI) est d'élaborer un processus d'approbation canadien qui peut être appliqué aux nouvelles technologies dans le domaine de la létalité atténuée. Un contrat a été adjugé à Alcea Technologies afin que cette entreprise passe en revue divers processus d'approbation et ce, dans le but de répertorier les éléments communs qui pourraient être appliqués au processus d'approbation canadien relatifs aux armes à létalité atténuée.

L'entrepreneur a fait l'inventaire des intervenants, des rôles et responsabilités, du cadre de gouvernance, des processus de haut niveau et des documents pertinents utilisés dans le cadre des processus d'approbation des armes à létalité atténuée en vigueur aux États-Unis et au Royaume-Uni. De plus, l'entrepreneur a recensé les différents processus d'approbation canadiens liés au matériel médical, aux appareils de télécommunication, aux véhicules aériens sans pilote, à l'homologation de l'ACNOR et à l'utilisation du dispositif d'aveuglement Laser Dazzler par les Forces canadiennes en Afghanistan.

Ce rapport présente les résultats des recherches de l'entrepreneur, il répertorie les éléments communs parmi les différents processus et fait des recommandations concernant les étapes qui devraient être suivies dans un processus d'approbation des armes à létalité atténuée.

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Executive summary

Toward the Development of a Canadian Less Lethal Weapons Approval Process: A Study of Contemporary Approval Process Models

Goodman, L; Wood, D; DRDC CSS TM 2011-17; Defence R&D Canada – CSS; October 2011.

Background: This study was in partial support of a larger project (Conducted Energy Weapons Strategic Initiative – CEWSI) in partnership with Public Safety Canada to provide further information on Conducted Energy Weapons (CEW) for law enforcement. CEWSI high level objectives are to recommend a CEW test procedure and comprehensive performance measures for possible inclusion in a Canadian national guidance for CEWs; convene a panel of medical experts to evaluate existing research to identify gaps in the research and to recommend steps to address those gaps; and to develop a Less Lethal Weapons (LLW) approval process that could be applied to emerging less lethal technologies. The aim of this study was to examine a span of various CEW and non-CEW technology approval processes, and describe the key stakeholders, including their roles and responsibilities, governance of these processes, the sequence of activities within each process, and to identify supporting documentation. The approval processes examined included: the United States LLWs, United Kingdom LLWs, Industry Canada telecommunications devices, Health Canada medical devices, Transport Canada unmanned air vehicles, Canadian Forces laser dazzler, and the Canadian Standards Association.

Results: Each approval process is described by process mapping charts, with key stakeholder roles and responsibilities and documents identified. The only example of a functioning and mature LLW or device approval process available is the UK's version. With the exception of the United States (which does not have a clear approval process but receives many inputs on LLW S&T and usage from academia and National Institute of Justice), there is clear accountability for the approval processes and there is a centralized functional authority. Where formal technical standards exist, testing is done by accredited labs and validated by the approval authority. Where formal standards do not exist, a risk management approach is taken that includes broader consultation. Where the technology area is particularly complex, the approval process is split into different classes/categories. Where requests for approval are initiated by users, the request is supported by a documented operational requirement whereas requests for approval initiated by manufacturers are supported by defined standards.

Significance: There are several elements in each of the processes presented that could be applied to a Canadian approval process for Less Lethal Weapons. These include a governance process that mirrors key elements in the UK model, incorporation of a risk management process, statement of operational requirement initiated and endorsed by the user community, transparent and third-party independent assessments (technical, medical and operational), legal advice, a public affairs component, development of tactics and procedures, a scientifically-based operational trial, and feedback/validation through a variety of communities and mechanisms.

Future plans: The results of this study will be presented to the Federal/Provincial/Territorial CEW Working Group for consideration in the development of a Canadian Approval Process for Less Lethal Weapons.

Sommaire

Vers l'élaboration d'un processus canadien d'approbation des armes à létalité atténuée : une étude des modèles de processus d'approbation contemporains

Goodman, L; Wood, D; DRDC CSS TM 2011-17; R & D pour la défense Canada – CSS; October 2011.

Contexte : La présente étude venaient partiellement appuyer un plus vaste projet (l'Initiative stratégique sur les armes à impulsions – ISAI) en partenariat avec Sécurité publique Canada afin de réunir plus d'information sur les armes à impulsions (AI) pour les organismes d'application de la loi. Les objectifs de haut niveau de l'ISAI sont de recommander une procédure d'essai pour les AI et des mesures globales de rendement qui seraient possiblement incluses dans un guide national canadien pour les AI; convoquer un groupe d'experts en médecine afin qu'il évalue les recherches existantes et répertorie les lacunes présentes dans la recherche et qu'il fasse des recommandations sur les étapes à suivre pour corriger ces lacunes; et élaborer un processus d'approbation des armes à létalité atténuée (ALA) qui pourrait être utilisé pour les nouvelles technologies associées à la létalité atténuée. Le but de cette étude était d'examiner la portée de différents processus d'approbation des technologies liées aux AI ou sans lien avec celles-ci et de décrire les principaux intervenants, incluant leurs rôles et responsabilités, la gouvernance de ces processus, la séquence des activités au sein de chaque processus et de répertorier les documents d'appui. Les processus d'approbation examinés sont les suivants : les processus d'approbation des AI des États-Unis et du Royaume-Uni, celui portant sur les appareils de télécommunication d'Industrie Canada, celui de Santé Canada sur le matériel médical, celui sur les véhicules aériens sans pilote de Transport Canada, celui sur le dispositif d'aveuglement Laser Dazzler des Forces canadiennes et celui de l'Association canadienne de normalisation (ACNOR).

Résultats : Chaque processus d'approbation est décrit à l'aide de schémas de description de processus où sont indiqués les rôles et responsabilités des principaux intervenants et les différents documents. Des deux processus d'approbation d'ALA étudiés, le plus achevé est celui du Royaume-Uni. Les processus d'approbation sont dotés d'une obligation de rendre compte clairement établie ─ sauf aux États-Unis ─ et il existe une autorité fonctionnelle centralisée. Lorsqu'il existe des normes techniques, les essais sont menés par des laboratoires agréés et les résultats sont validés par l'autorité d'approbation. Lorsqu'il n'existe pas de normes officielles, on utilise une approche de gestion du risque qui comprend une plus vaste consultation. Lorsque le domaine technologique est particulièrement complexe, le processus d'approbation est divisé en différentes classes ou catégories. Lorsque les demandes d'approbation sont faites par les utilisateurs, la demande est appuyée par un besoin opérationnel bien établi alors que les demandes d'approbation faites par les fabricants sont appuyées par des normes définies.

Importance : Plusieurs éléments dans chacun des processus présentés pourraient être utilisés dans le processus d'approbation canadien sur les armes à létalité atténuée, notamment un processus de gouvernance qui reprend les éléments clés du modèles du Royaume-Uni, l'incorporation d'un processus de gestion du risque, un énoncé des besoins opérationnels demandé par la communauté des utilisateurs, des évaluations (techniques, médicales et opérationnelles) transparentes et indépendantes effectuées par une tierce partie, de la consultation juridique, une composante des affaires publiques, la mise au point de tactiques et de procédures,

des essais scientifiques à l'échelle réelle et des commentaires et de la validation provenant de différentes collectivités et mécanismes.

Perspectives : Les résultats de cette étude seront présentés au Groupe de travail fédéral/provincial/territorial sur les AI afin qu'il en soit tenu compte dans la mise au point d'un processus d'approbation canadien des armes à létalité atténuée.

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Acknowledgements

The authors would like to acknowledge the significant contribution of Michael Verrilli who conducted the initial research and investigation into each of the approval process processes studied. Also integral to providing clearer understanding of Transport Canada's unmanned air vehicle approval process was Ms Karen Tarr, Inspector of Special Flight Operations. Several individuals were extremely helpful in assisting our understanding of Health Canada's medical device approval process, including Dr. Beth Pieterson, Director General, Environmental and Radiation Health Sciences Directorate, Healthy Environments and Consumer Safety Branch, and Dr. Roland Rotter, Medical Device Bureau, Therapeutic Products Directorate, Health Products and Food Branch, Health Canada. We also wish to thank Dr. Joe Cecconi, Program Manager, Research & Technology Development Section, U.S. National Institute of Justice (NIJ) who provided great detail into the NIJ's Less Lethal Weapons (LLW) Science and Technology programs and S&T networks, and Mr Graham Smith, Capability Advisor, Home Office Centre for Applied Science and Technology (HOCAST), who provided additional clarification of the United Kingdom's LLW approval process.

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1 Introduction

1.1 Background

The International law Enforcement Forum (ILEF) describes Less Lethal Weapons (LLWs) as devices that are less likely to result in death or serious injury than conventional firearms and/or munitions [1]. LLW are described as a broad array of weapon systems or devices that may incapacitate, disrupt, or deter individuals/groups from continuing a violent action or penetrating a boundary or facility, but are not intended to cause serious injury or death [2]. The technical methods or mechanism of action exploited range from chemical, energetic, biological, physical, electrical and psychological. A comprehensive review of the state-of-the art of LLWs is beyond the scope of this paper [1].

A number of high profile incidents in Canada have brought increased interest in police use of force and specifically the use of LLWs, particularly Conducted Energy Weapons (CEWs), by Canadian police services. There is increased scrutiny not only on the use of CEWs in specific instances, but also the method by which the devices were selected and tested and the measures taken to ensure public safety in their use. In November 2007, a Federal/Provincial/Territorial (FPT) CEW Working Group was created to support ongoing dialogue and information sharing on CEW policies and practices. In October 2010, the (FPT) Ministers Responsible for Justice approved both national guidelines for the use of CEWs and a national research agenda.

In response to a request from the FPT CEW Working Group, the Conducted Energy Weapons Strategic Initiative (CEWSI) was created as a project funded by the Canadian Police Research Centre (CPRC) and managed by Defence Research and Development Canada (DRDC) under the Centre for Security Science. The high level objectives of the CEWSI project [3] are to:

a. Develop a CEW test procedure and performance measures for current models in use in Canada as an immediate and interim measure to ensure CEWs are meeting manufacturer's technical specifications;

b. Recommend a CEW test procedure and develop comprehensive performance measures for possible inclusion in a Canadian national guidance for CEWs employment in Canada as part of an enduring capability;

c. Convene a panel of medical experts to conduct an independent evaluation of existing research to examine the physiological impact of CEWs, to identify gaps in the research and to recommend steps to address those gaps, and

d. Develop a Less Lethal Weapons approval process that could be applied to emerging less lethal technologies.

[1] Note: The term Less Lethal Weapons is alternatively termed: *Less Lethal Devices* by various agencies, particularly National Institute of Justice, so as definitively differentiate between the intent to inflict bodily harm/death, vs. the intent to immobilize/retard/repel with none or minimized bodily harm. There is currently much debate on this terminology and an in-depth discussion on terminology is beyond the scope of this paper. Consequently for the purpose of this paper, the term LLW will be used for convenience.

Currently, there is no national process for the regulation, approval and testing of LLWs in Canada. LLW use is regulated and determined by individual police forces, with some provinces establishing provincial guidelines and policies for approval and use.

As an initial step to developing a LLW approval process, the CEWSI project contracted a review of several approval processes to identify elements that could be applicable to a Canadian LLW approval process. The purpose of the contracted work was to survey a number of diverse approval processes –not only those that include CEW/LLW use, but also others which describe approval of other technologies. The aim was to examine the scope, characteristics, processes, governance, stakeholders, and document requirements. The resulting paper consolidated the outcome of each of these approval processes into a synthesis of differences and commonalities, and finally, provides starting point for recommending a Canadian LLW approval process. This work was conducted by SoftSim Technologies, Inc and was used to inform the content of this report.

1.2 Scope

The following approval processes were reviewed as part of this study:

a. LLW approval process for the United States (US),

b. LLW approval process for the United Kingdom (UK),

c. Approval of the Non-Lethal Laser Dazzler (NLLD) for the Canadian Forces (CF) in Afghanistan,

d. Approval of telecommunications devices by Industry Canada,

e. Approval of medical devices by Health Canada,

f. Approval of Unmanned Air Vehicles (UAVs) by Transport Canada, and

g. Accreditation of equipment by the Canadian Standards Association (CSA).

For each of the above approval processes, the following elements were reviewed:

a. Scope,

b. Stakeholder Roles and Responsibilities,

c. Governance,

d. High-Level Processes, and

e. Supporting Documentation.

Section 2 of this report contains a summary of the above elements for each of the studied approval processes.

Section 3 contains an analysis of the common points in each of the above approval processes with an emphasis on the linkage to a potential Canadian approval process for LLW.

Section 4 describes a number of building blocks that should be included in a Canadian approval process for LLW.

Section 5 presents our conclusions. In the concluding chapter we present suggested components of a potential Canadian LLW process. These are derived from best practices observed within the models studied, as well as the most applicable components to the Canadian context.

Finally, it is important to outline that it was outside the scope of this study to investigate the costs and timelines related to the approval processes studied. Each approval process contains differing time-lines inherent to their approval process (given unique conditions, governance, funding models and technologies). This information cannot be extrapolated to provide information of value to any future Canadian LLW approval process.

1.3 Methodology

A broad range of International and Canadian device approval processes were first selected for study. Some of these approval processes were LLW systems (two international examples and one Canadian example). The majority of approval processes surveyed are those employed across a range of functions inside the Canadian Federal Government. The intention of selecting a broad range of these selected device approval processes was to capture sufficient samplings of different processes and similarities, so that a greater collection of individual components of these might emerge to be applicable to a future Canadian LLW approval process.

The device processes were investigated using a combination of web-based searches, research through published documents, direct interviews with device/agency/departmental stakeholders, and interviews with specialists and experts in LLW processes and Science and Technology (S&T) activities (specifically in the case of the three LLW approval processes studied).

The resulting contractor report was used as a primary source of the information contained in Section 2 of this report. The authors then conducted analysis of the various processes to identify the common elements and to recommend building blocks for a Canadian LLW approval process.

2 Approval Processes

2.1 United States Less Lethal Weapons Approval Process

2.1.1 Scope

The United States (US) does not have a single centralized process that is used by all law enforcement agencies to approve the use of less lethal weapons therefore the following sections outline key elements that are emerging as best practices through NIJ.

2.1.2 Limitations, Restrictions and Constraints

State laws are powerful within the U.S. Constitution relative to Federal laws, and hence, no Federal use of firearms policy applies to the States. Accordingly, as there are many thousands of individual police forces in each State/municipality, rendering a federal LLW approval process is impossible, as decisions are made locally based upon individual law enforcement needs

Furthermore, under the Federal Bureau of Alcohol, Tobacco, Firearms and Explosives, [4] CEWs are not considered a firearm, and civilian acquisition and use of CEWs and other LLWs are not regulated. However in some states, the use of attenuated (reduced electrical energy) LLWs are permitted for use and sale by private citizens.

Thus, due to the historical, constitutional and cultural environment within the U.S., there is resistance to any centralized oversight function for LLWs and establishment of Federal approval processes or standards.

2.1.3 Stakeholders

Despite the lack of national and coordinated LLW approval processes in the US, there are several key stakeholders who interact and provide services to numerous law enforcement agencies. They are described below.

a. **The National Institute of Justice** (NIJ) is the research, development and evaluation arm of the US Department of Justice. The NIJ derives its authority from the U.S. Omnibus Crime Control and Safe Streets Act of 1968, as well as from the Title II of the Homeland Security Act of 2002. They provide funding "to identify, develop, and evaluate new or improved devices and other technology that will minimize the risk of death and injury to law enforcement officers, suspects, prisoners, and the general public" [5]. This stakeholder provides a strong focus to LLW science and technology, and serves various National, State and Municipal policing organizations through direct programs on new LLWs S&T. NIJ also collaborates with other Federal and State law enforcement entities such as the Department of Defence, the Federal Bureau of Prisons, Joint Non-Lethal Weapons Program, National Institute of Standards and Technology (NIST), International Association of Chiefs of Police, and the Royal Canadian Mounted Police (RCMP). In addition, NIJ works with selected

medical S&T institutions to promote a program of CEW and LLW incident reporting. Finally, NIJ is a key oversight and support component of the Penn State University-centered Technology Working Group on LLWs technology evaluation process (see below)[5][6].

b. **The U.S. Federal Bureau of Prisons** (FBP) is a stakeholder by virtue of joint technology demonstration trials with NIJ (through a separate infrared energy LLW proof of concept study). Federal guards carry weapons, but are reluctant to use these in many situations where less lethal force options would be more appropriate (i.e., during dispersion of violent inmates, mitigating violent encounters between individual/groups of inmates). NIJ is partnering with FBP's to explore LLW technologies as solutions in this environment and serves as scientific advisor in this regard.

c. **The National Institute for Standards and Technology** (NIST) is a federally-funded organization that is beginning to set national science-based standards for LLW testing and training, interacting with many law enforcement agencies.

d. **Department of Defence** (DoD) In particular, DoD's Joint Non Lethal Weapons Program (JNLWP) is a stakeholder by virtue of joint development of specialized long-range conducted energy weapon entry deterrence systems for use in operational theatre in addition to other non lethal weapons. DoD invests in LLW technology development through their own LLW Centre of Excellence, and partners extensively with NIJ in new technology demonstration projects.

e. **Penn State University Weapons and Protective Systems Technology Centre – Technology Working Group (TWGs).** There is a TWG for less lethal devices which supports the research development, test and evaluation process that occurs within NIJ's Office of Science and Technology program. The LLW TWG is housed within Penn State University, but its process is in lockstep with NIJ's mandate. The TWG identifies new technology needs, while the NIJ defines the operational requirement and potential solutions. If necessary, NIJ (or its other S&T partners) tests and evaluates these solutions and verifies safety, facilitates a LLW demonstration, and assists in technology transfer. The TWG also performs a peer review of the NIJ's LLW technology evaluation plan and subsequent implementation (which includes peer review panels, and hiring of grantees to perform the work). [7] The interaction between the TWG and NIJ's functions are depicted in Figure 1.

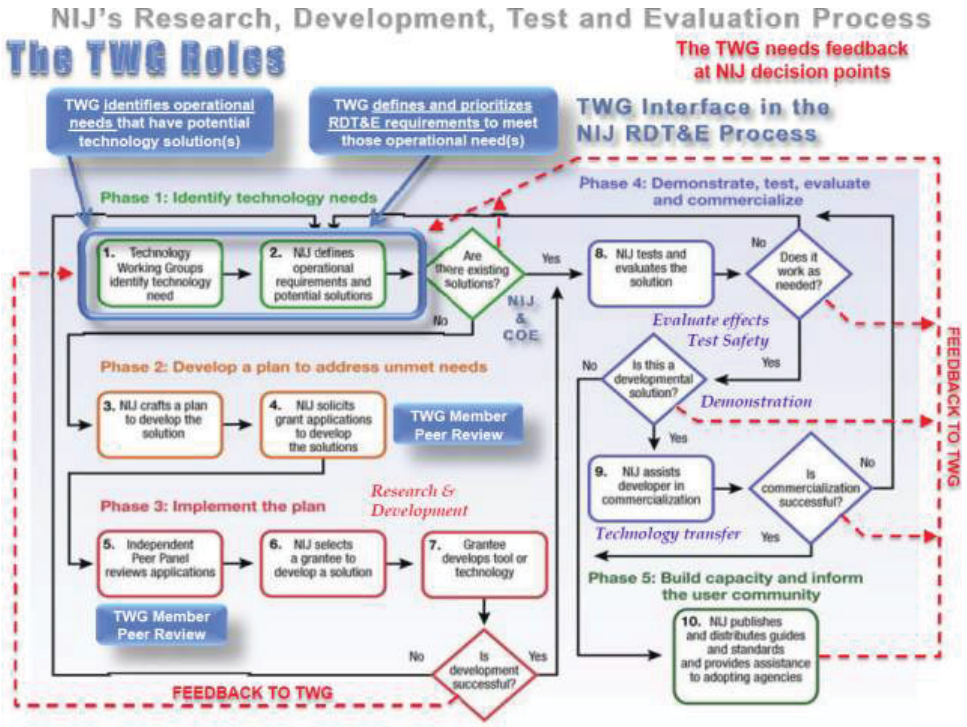

Figure 1: Process Flow diagram outlining Penn State University's technology Working Group and NIJ's functions with regard to development, testing and evaluation of less lethal devices in the US (Source: NIJ)

f. **Wayne State University.** Wayne State University is another center of expertise established by NIJ (in addition to Penn State above). Wayne State University provides coordination support for a medical panel to advise on medical effects of specific less lethal technologies for federal, state and local enforcement and correctional agencies' personnel.

g. **Wake Forest School of Medicine.** A piloted centre of excellence established by NIJ to directly involve the medical community on the effects of LL technologies.

2.1.4 Governance

As discussed above, there is a decentralized governance structure for LLW approvals in the U.S. Many ad-hoc agencies and organizations recommend usage, testing, policy and inform international partners, but these follow no Federally-mandated policy or law.

2.1.5 Approval Process

There is no approval process at the Federal level. While LLW approval processes may exist at the State and Municipal level, these were not investigated given the scope of this paper. The reader is directed to open-source sites for more information on these processes/policies where listings of numerous LLW usage/policy programs can be found [7]

2.2 United Kingdom Less Lethal Weapons Approval Process

The United Kingdom (UK) has the more mature of the two international LLWs approval processes investigated. The UK is a parliamentary democracy, similar to Canadian values and culture; however, some distinct differences exist between the UK and Canada in law, governance, structure, and policing legal process. For example, there is no National Police Force in the UK; in contrast, Canada has one national police force, Royal Canadian Mounted Police (RCMP), which for governance purposes, falls under the Minister of Public Safety. The UK has no national police force, but does have a unified policing code and central governance, which is managed centrally by the Home Office (HO), and Home Secretary. Policing in the UK is historically an unarmed service, but has armed itself more so during the last 30 years with dedicated Authorised Firearms Officers. In contrast policing is a provincial responsibility in Canada with each province establishing its own legislation and policy.

2.2.1 Scope

The UK LLW approval process is highly centralized, and is based upon the Home Office – published *The Code of Practice on Police Use of Firearms and Less Lethal Weapons*. The purpose of the code is to articulate selection, testing, acquisition and use of LLWs (as a subset of all firearms) by police [9][10]

The code specifies standards of use, device testing, training, and post-incident best practices. It includes any firearms and LLW available or considered for issue within any UK police force. This code came into practice in 2003, but is under review and due for re-release April 2011. The following currently outlines the intent of the code:

> "Chief Officers of Police will make arrangements under this code for authorization, deployment, and use of weapons requiring special authorization, taking account of detailed operating guidance updated and adopted collectively by chief officers of police. Guidance in respect of weapons requiring special authorization is set out in the Manual of Guidance on Police Use of Firearms."
>
> ACPO (2010) 'Manual of Guidance on Management, Command and Deployment of Armed Officers' highlights the importance of the professional responsibility placed on the Police Service to intervene in potentially violent situations to protect the rights of all persons, the need to ensure that human dignity and rights are upheld and that firearms should only be operationally discharged when absolutely necessary. These principles are set out in the **United Nations Code of Conduct for Law Enforcement Officials** adopted by the General Assembly resolution 34/169 of 17 December 1979 and the **United Nations Basic Principles on Use of Force and Firearms By Law Enforcement Officials** (as adopted by the UN Congress on Prevention of Crime and Treatment of Offenders, Havana Cuba 27 August to 7 September 1990)." [11][12]

2.2.2 Limitations, Restrictions and Constraints

Research into new LLWs is coordinated by the Home Office Secretary of State, but may also be conducted by independent police forces. In some cases, where mature solutions to LLWs requirements do not exist, there is an ability within the UK approval process to initiate an R&D project. The details pertaining to these individual projects are beyond the scope of this analysis and therefore not included in this paper. The following sections focus on the activities related to the introduction of mature technologies.

2.2.3 Stakeholders

The following stakeholders play a role in the UK LLW approval process:

a. The UK **Association of Chief Police Officers (ACPO)** for England, Wales N. Ireland (ACPO(S)- Scotland) is responsible for defining the operational requirements. They also oversee projects and coordinate the development of guidelines and training.;

b. **Home Office (HO)** is the lead central authority for establishing and maintaining policing policy in the UK (and is represented in the Prime Minister's cabinet by the Home Secretary);

c. **Home Office Centre for Applied Science and Technology (CAST)** is part of HO, and manages and conducts research and assessment of weapon systems, including LLWs, on behalf of government, police and other agencies;

d. The UK **Defence Science and Technology Laboratories (DSTL)** participate in joint S&T on weapon systems and LLWs for HO. DSTL provide biomedical assessment of weapon systems which is fed into the independent medical committee;

e. **National Policing Improvement Agency (NPIA)** is a separate body that develops policing doctrine and training for UK police forces, and consults with HO and ACPO;

f. **Defence Scientific Advisory Council (DSAC) Sub-Committee on Medial Implications of Less Lethal Weapons (DOMILL)**. DOMILL is a committee of independent clinicians reporting to the Secretary of State for Defence. They provide "advice on the biophysical, biomechanical, pathological and clinical aspects of generic classes of LLWs; independent statements on the medical implications of use of specific LLW systems; and advice on the risk of injury from specific LLW systems". In addition to an official government member, the sub-committee is comprised of the following medical specialty areas: Clinical toxicology, neuro-physiology, general surgery, anaesthesia, toxicology, trauma surgery. Where required, the sub-committee will consult with other experts for input. In its medical advisory role, DOMILL will also consider both commercial off-the-shelf, as well as systems designed for unique operational purposes. It will consider operational usage, manufacturing process, operating environment, and will monitor any LLWs changes and technical alterations. Thus, all elements of LLW systems are considered by

DOMILL: use policy, user guidance, training syllabus, equipment maintenance, environmental factors (heat, cold, moisture, etc.), accuracy and consistency, human and animal effects, and operational data if available. Since 2002, DOMILL has issued five statements on CEWs. [13]

2.2.4 Governance

The approval authority for LLWs for the police is the Home Secretary. The Home Secretary is represented in the Prime Minister's Cabinet, and recommends policy for policing in UK; this is ultimately voted into law by Parliament.

2.2.5 Approval Process

The UK LLW approval process is outlined below, and depicted graphically in Figure 1.

The first step in the process involves the ACPO who convene working groups to produce an operational requirement (OR). Next, CAST, along with DSTL providing biomedical input evaluate commercial/off the shelf (COTS) LLW products in relation to previously developed perational requirements, and reports to ACPO: Three COTs categories A, B, C are created for study:

A: likely meets OR;

B: possibly meets OR, and warrants further research over an extended timeframe;

C: do not meet OR's and therefore do not warrant further consideration.

When industry cannot meet operational requirements, the Home Office may initiate a development project for new LLWs that meet a new or unique operational requirement.

The next step in the approval process involves development of operational guidelines and policy for LLW use. This step is augmented by information provided by vendors, and evaluations conducted by CAST and DSTL Work may also be carried out at this stage to supplement any available information on the medical effects of the use of the LLW. Any work will be particularly tailored to use as described in the guidelines and policy.

An independent medical panel (DOMILL) is also employed to assess the implications of deploying LLWs in UK Police Forces. This includes reviewing medical effects of LLWs, and gaps in knowledge regarding medical complications stemming from an untoward incident. Studies undertaken by CAST and DSTL are also considered by the panel. DOMILL will provide a statement to ministers on their views on the medical implications of deploying the less lethal option in question.

The information is then subjected to ministerial review, which based on a collective review of the technical, medical and operational requirements of the LLW, may recommend the device to be taken forward to an operational trial by police. The Home Secretary has the ultimate power to approve or deny the LLW upon consideration of all the data/evidence.

An operational trial is then conducted, which is limited to a selected or representative small number of police forces. The LLW ‘s impact and effectiveness is evaluated in a similar process to the one outlined above, including a medical assessment and an assessment of effectiveness. . Following this step, extension to all UK Police forces for use may be approved.

Post-deployment committees are stood up to monitor and provide feedback from a medical (DOMILL), technical and operational perspective on the continuing use of the device.

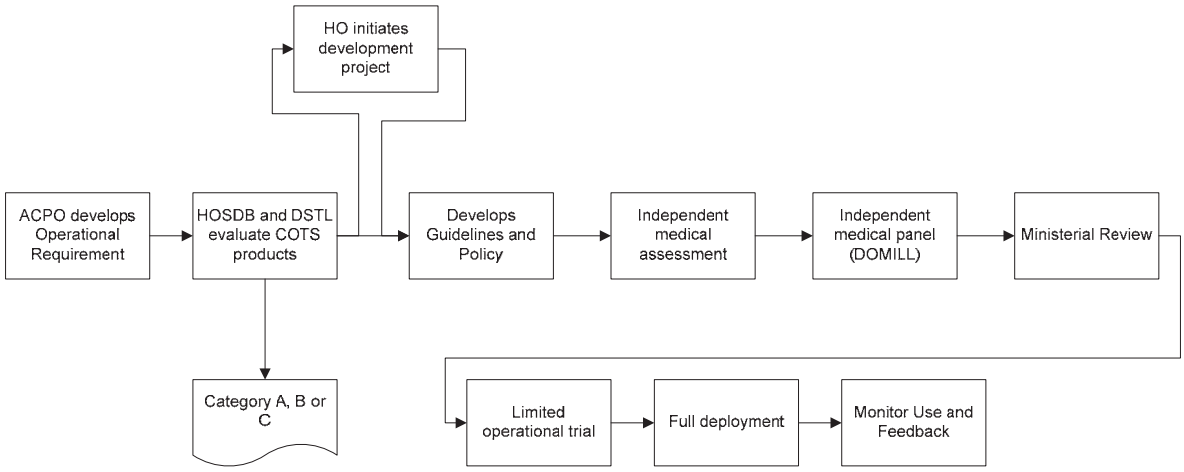

Figure 2: UK LLW Approval Process

2.2.6 Supporting Documentation

The following documents are required within the UK LLW approval process:

a. The Operational Requirements (owned by ACPO)

b. The Technical Specification, Standard or Test Protocol (produced by CAST based on the OR)

c. A report on the technical assessment (CAST)

d. An report on any medical assessments (dstl)

e. Guidelines and policy for the use of a less lethal option by the UK police are produced (by ACPO)

f. A Statement on the Medical Implications of Use (DOMILL)

g. A Statement from the Home Secretary supporting a Trial

h. Independent report on the Operational Trial

i. A further Home Office Statement supporting full Operational Use

2.3 Health Canada Approval of Medical Devices

Although health care delivery in Canada is the jurisdiction of the provinces, medical devices are approved and regulated by the federal government. Health Canada (HC) has a well developed, highly bureaucratized and detailed process for medical devices approval that is outlined below. Full details on HC's medical approval process is available elsewhere [13]

2.3.1 Scope

Health Canada (HC) is the lead agency in Canada who administers the medical device approval process, with over 450,000 Class I and over 860,000 Class II, III and IV devices currently in the marketplace (or in use in a variety of health care delivery venues) which have been evaluated by HC

The aim of the process is to provide Canadians access to safe and effective medical devices. While all devices have the potential to cause harm to a patient or user, Health Canada uses a risk-based approach to the regulation of these products. While moderate to high risk medical devices (Class II – IV) require Health Canada approval to be sold in Canada, the provinces, which constitutionally have jurisdiction over health care, control which devices will be covered under their respective plans

A rules based classification system was developed by Health Canada to categorize medical devices according to their potential risk into one of four classes; Class I represents the lowest risk devices and Class IV represents the highest risk devices. The degree of regulation imposed on an device is proportional to the risk. The following indicators of risk were used to create the rules: the degree of invasiveness, duration of contact, body system affected and local versus systemic effects [15]:

a. **Class I**: active medical devices which do not transmit energy to the patient (e.g. dental curing lights), non-invasive devices (e.g. eyeglasses), invasive devices (e.g. re-useable surgical instruments;

b. **Class II:** active medical devices that transmit energy to the patient (e.g. digital blood pressure monitor, TENS machine, X-ray equipment that works in radioactive mode), invasive devices that remain in the body less than 30 days (catheters, single use surgical instruments) and non-invasive devices that modify the biological or chemical composition of blood or other body fluids;

c. **Class III:** active medical devices that emit ionizing radiation, and transmit energy to the patient (eg. CT scanner, mammography machine, Excimer lasers for eye surgery), invasive devices that remain in the body for greater than 30 days (orthopaedic implants), and non-invasive devices that modify the biological or chemical composition of blood or other body fluids (dialyzers, apheresis machines;

d. **Class IV**: active implantable medical devices (eg pacemakers, defibrillators), invasive devices that remain in the body for greater than 30 days (eg breast implants, neurological shunts), devices that are incorporate animal and human tissue (eg. porcine heart valves, collagen dermal fillers).

Health Canada issues licences to manufacturers of Class II, III and IV devices. It does not issue licences for Class I devices but does regulate the safety of these devices should there be issues occurring when the product is in the marketplace. Health Canada does issue an Establishnment Licence to distributers and manufacturers for Class I devices, but they are for the facilities not the specific products.

2.3.2 Limitations, Restrictions and Constraints

This process does not necessarily inform or replace any further approvals for medical device required at individual sites of health care delivery (hospitals, clinics) in municipalities (which may be conducted by individual hospital/clinic biomedical technical departments)

Medical device approvals are subject to internal medical boards, which are derived from Health Canada staff, with the exception of special ad-hoc committees for cardiovascular devices (see below)

2.3.3 Stakeholders

The following stakeholders play critical roles in the approval of medical devices:

a. **Medical Device Vendors**: they submit their products for evaluation. Based upon formal feedback in the form of letter of approval/rejection, vendors are invited to appeal, or re-submit after making recommended changes to their devices.

b. **Health Canada's Medical Device Bureau** (MDB), is the federal regulatory authority which conducts pre-market safety/technical, scientific and medical evaluations on the submitted medical devices, as well as post-market safety assessments.

c. **Justice Department of Canada**: ensures that Federal legislation pertaining to medical device approval are adhered to, and liaises with HC.

d. **Canadian Nuclear Safety Commission**: ensures that Class II medical equipment involving nuclear isotopes is installed according to prescribed procedures and used in accordance with the Nuclear Safety and Control Act. HC must liaise with CNSC to ensure compliance prior to approving the device in question, and the vendor must also apply to CNSC in addition to HC for these types of medical devices.

e. **Standards Council of Canada**. In order to have a valid Quality Management Systems Certificate, 3rd-party auditors are also audited by this body.

f. **Special Ad-hoc Committees** (cardiovascular devices): With respect to special devices introduced, HC will occasionally form a special ad-hoc evaluation or scientific advisory committee derived from experts outside of government to evaluate their risk. The most common ad hoc committee stood up is the Scientific Advisory Committee on Medical Devices used in Cardiovascular System cardiovascular devices. A detailed conflict of interest and security clearance procedure is in place to maintain objectivity and transparency.

2.3.4 Governance

Health Canada is the lead federal department responsible for this approval program, and which contains the Medical Devices Program (MDP). The Medical Devices Bureau is one bureau in the Therapeutic Products Directorate (TPD) which is one of the Directorates in the Health Products and Food Branch of Health Canada.

The Medical Device Program (MDP) is organized within the HPFB, and has an $11M budget, and has 150 employees. It contains three directorates: Therapeutic Products Directorate (TPD) which undertakes premarket review and licensing and post-market risk assessement; Marketed Health Products Directorate (MHPD) which conducts post-market surveillance and risk communication; and Health Products and Food Branch Inspectorate (HPFBI) which tracks compliance, enforcement and inspection activities. Within theTPD is the Medical Device Bureaux (MDB), and is the body which undertakes the medical device approvals. MDB is divided into two divisions: Device Licensing Services Division and Device Evaluations Division. The organizational structure is depicted below in Figure 3. Sign-off of device evaluations is done at the MDB Director General level.

Department of Justice of Canada, under the Federal Food and Drug Act, under consultation with HC, ensures that legal requirements involving medical devices is undertaken

Finally, the Canadian Nuclear Safety Commission ensures adherence to nuclear standards and technical/safety requirements with devices that involve isotopes and radiation.

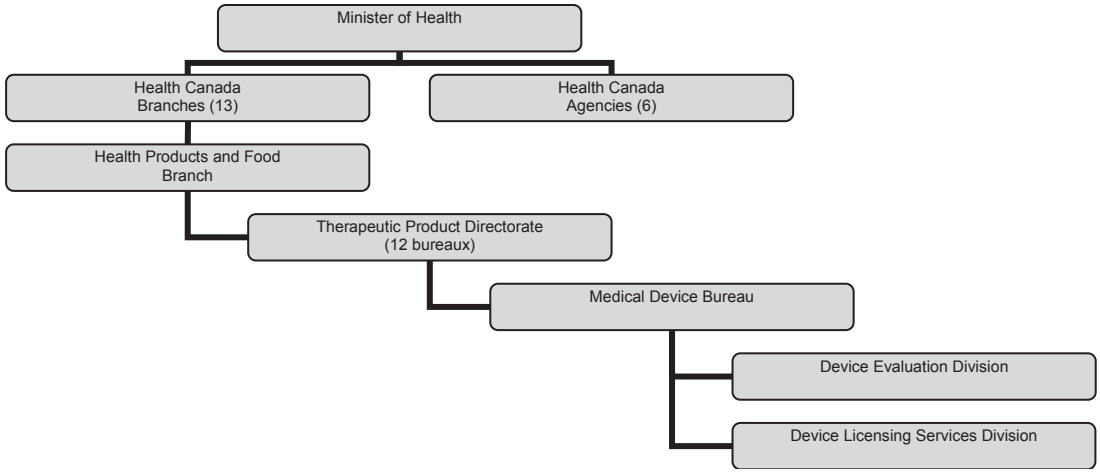

Figure 3: Organizational entities and structure within Health Canada responsible for medical device approval processes and administration

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2.3.5 Approval Process

The Approval process for HC medical device approval is outlined below, and graphically represented below in Figure 4.

The first stage of the approval process involves a premarket review. This is undertaken by the vendors for class III and IV devices. Vendors follow a template provided by HC. This review includes a scientific and medical review of safety and effectiveness.

The vendor then submits their application to HC's MDB. Each application must contain detailed information on intended use, features, list of other countries where already sold, including recalls, list of technical standards that apply, sterility verification, list of scientific studies and bibliography which validate safety and effectiveness, summary of investigational studies conducted in the case of in-vitro devices, and copy of quality management system certificates which verify compliance to CAN/CSA-ISO 13485:03. This review is in turn, audited by the Standards Council of Canada and Health Canada.

The approval process then becomes imbedded within HC's MDB which screens and evaluates the devices. Only in extremely rare cases, especially in the case of cardiovascular devices, is an ad-hoc Scientific Advisory Committee on Medical Devices used in Cardiovascular System is formed to evaluate the device in question. This ad-hoc committee is composed of non-government clinical/research experts across many sub-disciplines and across several national regions. The selection and identity of these individuals is transparent and is published within the HC medical approval web site. In some other instances, devices are evaluated by Device Evaluations Division's contracted-out experts (academia, medical clinicians etc.).

MDB evaluates Class III and IV devices for safety, completeness and effectiveness.

Next, letters of approval are sent to the manufacturers informing them of the licensing decision. If it is a negative decision, the manufacturer does have an ability to appeal the decision.

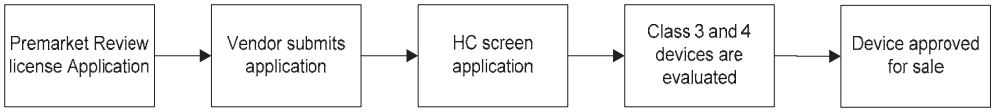

Figure 4: Canadian Medical Device Approval Process

2.3.6 Supporting Documentation

The following documents are required to support an application for medical device approval. A complete listing is available from the HC TPD web site [17]:

a. Vendor-initiated letters/application forms for device approval. There are numerous steps in this process. The key documents at this stage include:

    a) New Device License Application forms for Class II, III, IV devices

    b) Amendments for Class II, III or IV devices

    c) Private Label Devices

b. Declaration of Conformity form

c. Investigator's Agreement with Medical Devices Regulations.

d. HC Administrative letters (screening acceptance, deficiency, clarification request)

e. Acceptance/Rejection letters from HC

f. Withdrawal letter (vendor)

g. Letter of intent to repeal; 10 day timeframe

h. Comprehensive appeal document (with cross-referenced reference material); 20 day timeframe

2.4 Unmanned Air Vehicles

2.4.1 Scope

Under Article 101.01 of Transport Canada's Canadian Aviation Regulations (CAR) a UAV is "a power-driven aircraft, other than a model aircraft, that is designed to fly without a human operator on board." A model aircraft also has a specific definition: "an aircraft, the total weight of which does not exceed 35 kg (77.2 pounds), that is mechanically driven or launched into flight for recreational purposes and that is not designed to carry persons or other living creatures". [18]

It is understood that the UAV is part of a larger system that includes the air vehicle, a ground control station, and communications links (could have many including command and control, sense and avoid, air traffic control communications and payload). While some countries are using the term Unmanned Aircraft Systems, the legal terminology in Canada is still UAV.

UAVs are seeing increased use in a variety of commercial uses such as aerial surveying, railway and pipeline monitoring or geological surveying as well as government uses such as law

enforcement, border patrol, traffic control and weather tracking to name just a few. The policy objective related to the approval process applicable to UAVs is to ensure that UAV flights are operated with an equivalent level of safety as a manned aircraft.

The process outlined in this section covers the process for obtaining a Special Flight Operations Certificate (SFOC) which is required for all UAVs. Figure 3 outlines the decision process to determine whether or not a SFOC is needed and whether an abbreviated application can be made or if a full application is required. In summary, the following processes are identified: [19]

a. Model Aeronautics Association of Canada operating UAVs > 35kg for recreational purposes,

b. Simplified SFOC Application Process for remote controlled UAVs, <35kg and operated within visual range, and

c. Standard SFOC Application Process for all other cases.

Note that a SFOC is not required for model aircraft <35kg, that is operated by a member of an association for recreational purposes.

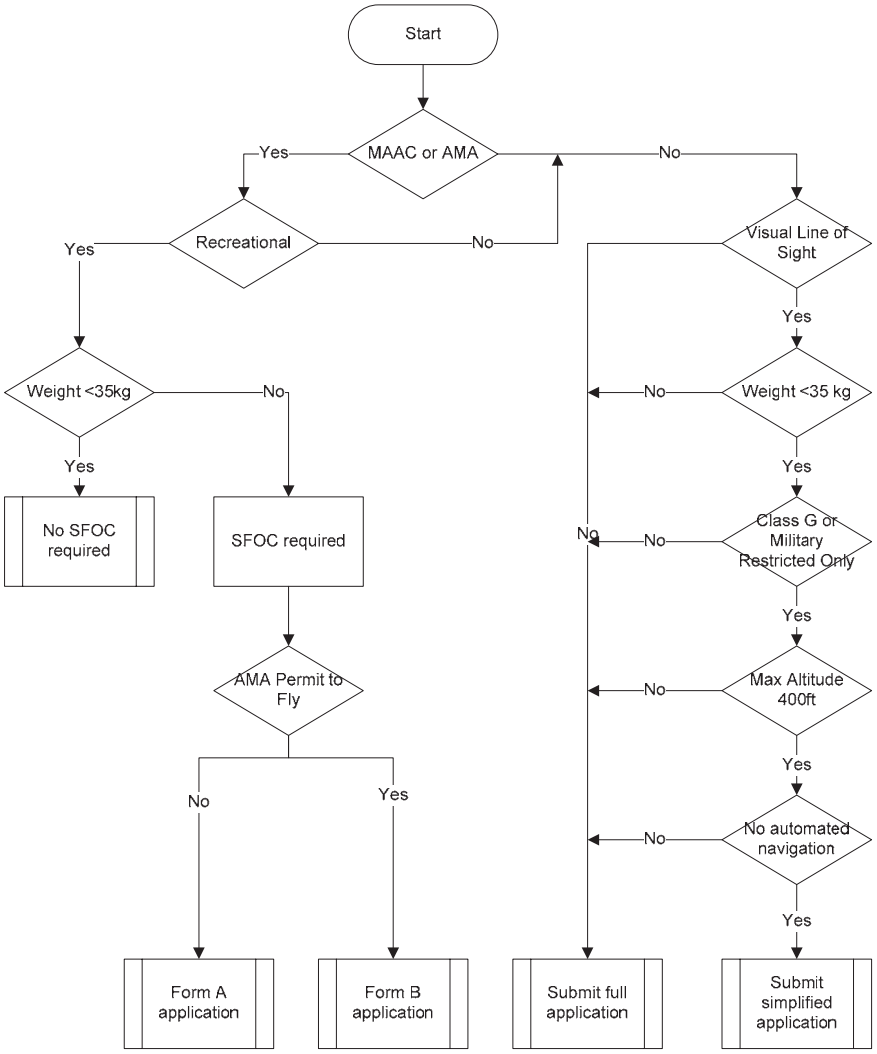

Figure 5: Special Flight Operations Certificate Decision Tree

2.4.2 Limitations, Restrictions and Constraints

The Canadian Aviation Regulations apply to all civilian aircraft. Military aircraft are exempt under article 102.01 of the regulations [18] when:

a. They are being manoeuvred under the authority of the Minister of National Defence, and

b. Military aircraft of a country other than Canada, where the Minister of National Defence has provided an exemption.

In the case where a UAV is being operated in restricted military airspace, the SFOC issued by Transport Canada will be issued in cooperation with National Defence.

Where the operator (i.e. ground station) of a UAV is not physically located in Canada, the operator is still required to obtain a SFOC and to be compliant with Canadian regulations while the UAV is in Canadian airspace.

A SFOC is normally issued for a specific mission and for a specific timeframe. A SFOC for a long-term or not-site specific situation will not be granted until the applicant has established a history of safe operations.

2.4.3 Stakeholders

The following organizations have a role in the approval process for UAV's:[19]

a. **Transport Canada** has the mandate to regulate issues related to Civil Aviation, including the UAVs, and is the functional authority for the Special Flight Operations Certificate approval process;

b. **Transport Canada Civil Aviation Inspectors** are responsible for reviewing applications for SFOC using the Staff Instruction as guidance and coordinating with any affected agencies;

c. **Transport Canada Regional Superintendent, General Aviation.** The signature on the SFOC will be the Superintendent of the regional office who reviews the entire application package;

d. **UAV Operators** are responsible for making the necessary application for a SFOC, arranging for the necessary insurance, obtaining an assigned frequency, and conducting an appropriate risk analysis;

e. NAV Canada, DND, Serco are all **airspace service providers** and are responsible for de-conflicting the use of airspace. If necessary, a Notice To Air Men (NOTAM) will be issued advising of planned activities;

f. **Transport Canada Aerodromes** and the **Air Navigation Branch** will be engaged in the situations where airspace needs to be restricted;

g. **Industry Canada** is responsible for the assignment of radio frequencies, spectrum and telecommunications issues in accordance with the *Radiocommunications Act*. As most UAVs are controlled by a ground station via radio link, a frequency may need to be assigned for the mission, and

h. The **Transport Canada Regional Enforcement Branch** deals with situations where UAV operations are being conducted without SFOCs.

2.4.4 Governance

The mandate of Transport Canada for air transportation and safety is governed by the *Aeronautics Act* [20] while the requirement for a formal Special Flight Operations Certificate for UAVs is specified in the Canadian Aviation Regulations [18].

Transport Canada has distributed a Staff Instruction for the issue of SFOCs for UAVs in order to ensure consistency in the application of policies, directives, standards and procedures among Headquarters and Regional staff.

Industry Canada is the authority for control of the frequency spectrum and the issuance of Radiotelephone Operations Restricted Certificates.

2.4.5 Approval Process

There are no technical standards that cover the manufacture or design of UAVs, but article 623.65 of the CAR does identify standards that apply to the operation of a UAV. [18] The entire approach for approval of a UAV mission is based on a risk management approach that calls for the operator to identify the risks and propose appropriate mitigation strategies.

Figure 5 outlines the approval process for a Special Flight Operations Certificate for UAVs.

It is the responsibility of the UAV operator to initiate the request for approval at least 20 days in advance to allow sufficient time to staff and approve the request. Section 2.4.6 identifies the information required for a complete application. It should be noted that the amount of detail required by Transport Canada is very extensive. The operator is also required to conduct all pre-planning activities such as:

a. Arranging for adequate liability insurance. A SFOC will not be approved without this.

b. Coordinating with appropriate airspace providers (either NAVCanada, DND or Serco),

c. Applying for radio frequency clearances with Industry Canada.

d. Conducting assessment of risk of injury or loss.

Using the Staff Instruction as a guideline, the Transport Canada Inspector will review the application and supporting documentation and conduct any required coordination with. The Inspector will request any other information required to determine the planned operation can be conducted safely. The Staff Instruction is provided to potential applicants to guide them in providing complete information for the Inspectors.

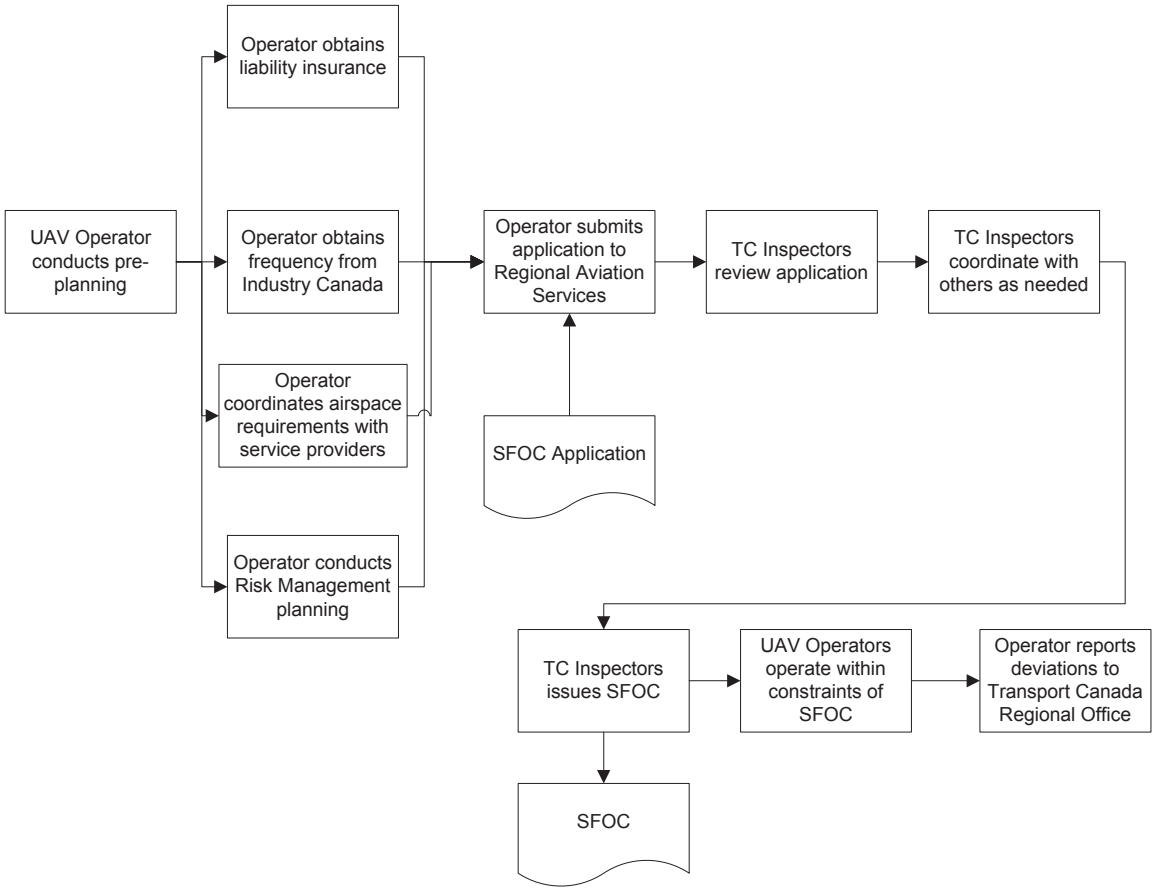

Figure 6: Special Flight Operations Certificate Approval Process

Once the Transport Canada Inspector is satisfied with the details of the information provided and has coordinated with other agencies, a SFOC will be prepared for the Regional Superintendent's signature.

Once the operation is complete, the UAV operator is responsible for reporting to TC any deviations from the plan or issues encountered during the operation.

The process for UAVs <35kg and operating within visual range is the same except the scope of information required is reduced. Also, an abbreviated process exists for members of model aircraft associations that would like to fly a UAV >35kg for recreational purposes. This abbreviated process is only available to the Model Aeronautics Association of Canada (MAAC) or the Academy of Model Aeronautics (AMA) with flight permits.

2.4.6 Supporting Documentation

The following documents are required to support the approval process for SFOC:

a. **Application**. The formal application will include the following items:

i. Contact information for applicant

ii. Contact information for the operator during the operation,

iii. Means of contacting the team during the operation,

iv. Type and purpose of the operation,

v. Dates, alternate dates and times,

vi. Complete description including pertinent flight data,

vii. Security plan for the area,

viii. Emergency contingency plan,

ix. Contact info for Ground Supervisor,

x. Detailed plan describing how the operation shall be carried out, and

xi. And any other necessary information

b. **Risk Management Plan**. The applicant is expected to identify the risks and plan for appropriate mitigation strategies. Some of the events to be considered include:

   i. Degradation or loss of: command and control links, telemetry data links, communications with air traffic controller, sense and avoid links, payload links, propulsion system, control station power, software system, or visual contact when operating within range;

   ii. UAV encounters with: another aircraft, varying weather conditions, airframe and engine icing, and

   iii. Aborted Take-off or Landing

c. **Radiotelephone Operations Restricted Certificate**. This is required for any radio operations and is issued by Industry Canada;

d. **Special Flight Operations Certificate**. This is the document signed by the Regional Superintendent that provides the authority for the UAV operation to take place as planned. The SFOC will identify conditions attached by Transport Canada.

2.5 Telecommunications Devices

2.5.1 Scope

The approval of telecommunications devices in Canada is in place to prevent radio-communication interference, harm to the Canadian public telecommunications networks, and to ensure the safety of personnel working on telecommunications facilities and the safety of users.[21] It is mandatory for any telecommunications equipment entering Canada to meet both technical standards and marking requirements established by Industry Canada.

There are three categories of telecommunications equipment:

a. **Telecommunications Apparatus**.

b. **Category I**. Radio and broadcasting equipment such as cordless and cellular telephones, and television broadcasting transmitters.

c. **Category II**. Radio, broadcasting and interference-causing equipment such as GPS receivers, television sets and fluorescent lights.

2.5.2 Limitations

Many international technical broadcasting standards exist, and Canada adopts these standards for the three classes of devices. Furthermore, foreign manufactures must comply with IC standards under a separate mutual recognition standard.

2.5.3 Stakeholders

The following stakeholders play a role in the approval of telecommunication devices.

a. **International Telecommunication Union (ITU)**. This international organization works with governments and industry to develop voluntary international technical standards for telecommunications equipment. Industry Canada then takes these standards and develops the Canadian regulatory standards;

b. **Industry Canada** is responsible for regulating telecommunications equipment in Canada;

c. **Manufacturers, importers distributors and vendors** are required to ensure all equipment meets the regulatory standards established by Industry Canada;

d. **Terminal Attachment Program Advisory Committee (TAPAC)** is a consultative committee organized by Industry Canada to discuss the technical regulation standards related to Telecommunications apparatus;

e. **Radio Advisory Board of Canada (RABC)** is an independent association of manufacturers, carriers, broadcasters, public safety, users, etc that provides advice

regarding the management and use of the radio spectrum including advising on the Radio Standards Specifications (RSS) and Broadcasting Equipment Technical Standards (BETS) that are used to approve Category I devices;

f. **Comité International Spécial des Perturbations Radioélectriques (CISPR)** develops international standards applicable to Category II devices that are adopted by Industry Canada;

g. **Test Laboratories** are engaged by the manufacturers to conduct required testing. As a minimum, they must be ISO/IEC 17025 compliant. A list of laboratories accredited to also certify terminal apparatus is available on the Industry Canada website at http://www.ic.gc.ca/eic/site/ceb-bhst.nsf/eng/tt00064.html ;

h. **Certification Bodies (CB).** Industry Canada recognizes specific organizations (companies) to certify Category I radio and broadcasting equipment. A list is available on the Industry Canada website at http://www.ic.gc.ca/eic/site/ceb-bhst.nsf/eng/tt00067.html ;

i. **Certification and Engineering Bureau.** This organization within Industry Canada provides a certification service for both radio and terminal equipment. The CEB reviews all submissions and those approved are added to the approved equipment lists.

2.5.4 Governance

Industry Canada has clear responsibility to regulate telecommunications equipment in Canada under Section 5 of the *Radiocommunications Act* and Section 69.3 of the *Telecommunications Act*. Under the Telecommunications Equipment Regulatory Process, the approval authority is decentralized to accredited test laboratories for Telecom Apparatus, to CBs for Category I devices and to the manufacturer for Category II.

2.5.5 Approval Process

The approval process is different for each class of device. Each is outlined below and represented in Figure 6:

a. **Telecommunications Apparatus**. For this equipment, the manufacturer is required to have the equipment tested by an accredited test laboratory. A Declaration of Conformity (DoC) to the CS-03 specification is issued by the test laboratory. The DoC, the test reports, contact information and registration fees are forwarded to the CEB. If satisfied, the CEB will add register the telecommunications apparatus and add it to the Terminal Equipment List (TEL);

b. **Category I**. For this equipment, the manufacturer selects a test laboratory that is ISO/ECS 17025 to conduct the testing. The results of the test are reviewed by a CB who will issue the certification and submit the certification file along with the test

reports and registration fees to the CEB. If satisfied, the CEB will add the Category I equipment to the Radio Equipment List (REL)

c. **Category II**. This classification of equipment is exempt from certification and registration and it is the responsibility of the manufacturer to arrange for necessary testing and marking to indicate it meets the required standards.

The telecommunications approval process has a strong compliance component. CBs are required to conduct market surveillance on 5% of the equipment they certify and on at least 1% of equipment subject to radio frequency exposure.

In addition to that, it is the practice of Industry Canada to conduct audits on a small number of Category I devices approved by CBs.

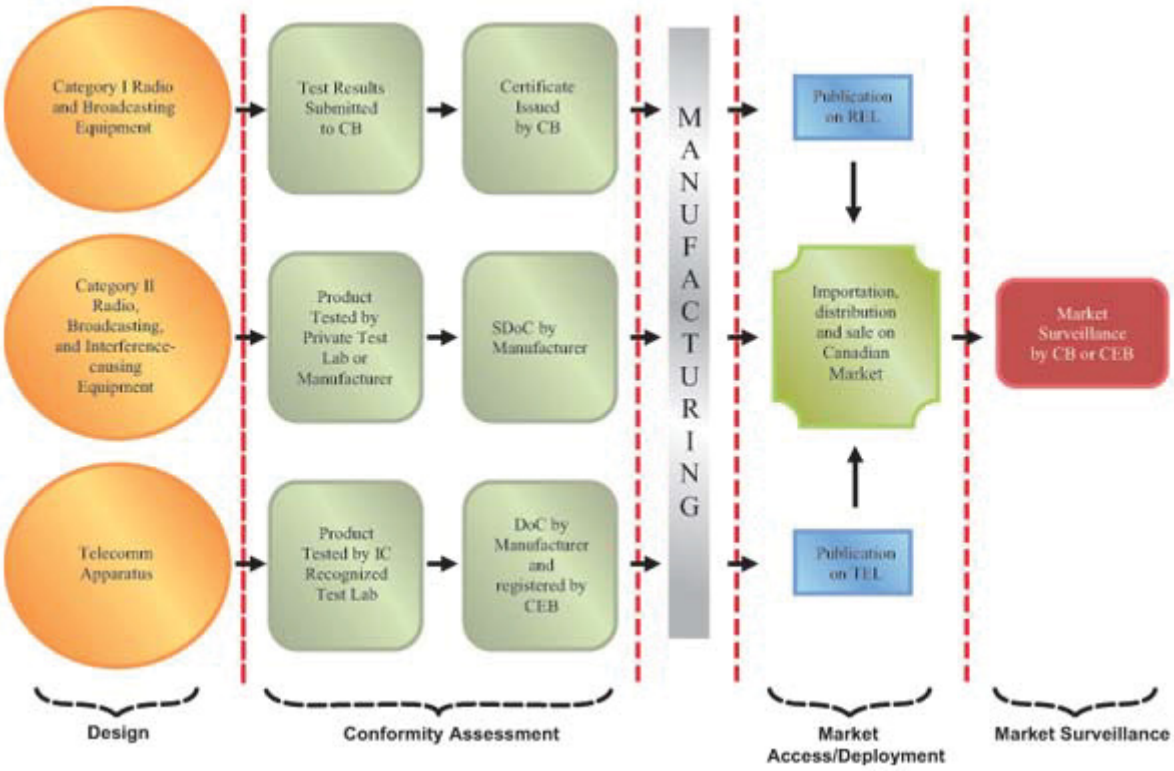

Figure 7: Industry Canada's Telecommunications Device Approval Process (source http://www.ic.gc.ca/eic/site/mra-arm.nsf/eng/h_nj00055.html)

2.5.6 Supporting Documentation

The following documents are key to the approval of telecommunications devices:[21]

a. **Standards**. Most of the devices are subject to technical and regulatory standards which are used for the approval process. Some of them include:

i. CS-03: Compliance Specification for Terminal Equipment, Terminal Systems, Network Protection Devices, Connection Arrangements, and hearing Aids Compatibility,

ii. Radio Standards Specifications (RSS),

iii. Broadcasting Equipment Technical Standards (BETS),

iv. Interference Causing Equipment Standards (ICES)

b. **Test Results**. All test results must be retained (10 years for Telecommunications Apparatus and Category I devices and 5 years for Category II devices);

c. **Declaration of Conformance**. This is issued by accredited test laboratories for Telecommunications Apparatus and submitted to CEB;

d. **Certification.** This is issued by CBs for Category I devices;

e. **Industry Canada approved equipment lists**. There are two: Radio Equipment List (REL) and Terminal Equipment List (TEL).

f. **Mutual Recognition Agreements/Arrangement (MRAs)**. These agreements allow countries to recognize the competence of other countries' test laboratories and certification bodies and thus expedite the approval process.

2.6 Canadian Forces Approval of Non-Lethal Laser Dazzler (NLLD) Device in Afghanistan

2.6.1 Scope

The Canadian Forces initiated a capital project to procure and put in service a non-lethal means to hail, warn, deter and dissuade vehicles or persons from encroaching during Canadian operations as an alternative to deadly force. The Non-Lethal Laser Dazzler was intended to deter people from approaching on foot, by bicycle, motorcycle car or truck by providing a clear warning that they are approaching too close.

2.6.2 Limitations, Restrictions and Constraints

The use of NLLD is restricted to use in Afghanistan, with no mandate to deploy this LLW in Canada other than for training. Approval of the NLLD required a full consideration and understanding of any legal implications (Criminal Code of Canada, Law of Armed Conflicts and Protocol IV to the UN Convention on Certain Conventional Weapons). In this regard, Protocol IV bans the use of laser weapons "specifically designed as their sole combat function or one of their combat functions, to cause permanent blindness to unenhanced vision" [22]

The NLLD project was implemented to select a warning and signalling device and not a device to purposely cause injury. The proposed equipment was therefore not considered to be a weapon.

The NLLD system was selected through a competitive bidding process through evaluation against the approved Statement of Operational Requirement. The entire approval process followed the Department of National Defence approval process applied to all capital projects.

2.6.3 Stakeholders

The following stakeholders played a role in the approval of the NLLD for use in Afghanistan [23]:

a. **Department of National Defence Program Management Board (DND PMB)**. This standing committee provided final approval of the project for the planned expenditures;

b. **Director of Land Requirements (DLR)**. DLR was responsible for producing the SOR and for managing the requirements throughout the project on behalf of the operators.

c. **Director General Land Equipment Program Management (DGLEPM)**. DGLEPM was the Project Leader and was responsible for overall management of the project.

d. **Senior Review Board (SRB)**. The SRB is comprised of representatives from all organizations that have a stake in the project. Although the SRB has no formal decision authority, they provide critical advice to the Project Leader;

e. **Subject Matter Experts (SMEs)**. Specific expertise was incorporated into the project team to ensure advice was available in the planning and implementation and specifically provided the formal risk assessment related to their areas. The following SMEs were part of the NLLD project team:

   iv. Medical Advisor,

   v. Laser Safety Officer,

   vi. Legal Advisor,

f. **External Policy Stakeholders**. The following external organizations were consulted for input as part of the legal review:

   vii. Department of Foreign Affairs and International Trade (DFAIT),

   viii. Privy Council Office, and

   ix. Department of Justice

d. **Defence Research and Development** (DRDC). DRDC Valcartier conducted technical evaluations on five proposed products.

e. **Operators.** The operators provided input to the Statement of Operational Requirement as well as participated in user trials of 2 proposed products.

2.6.4 Governance

The selection and approval of less lethal weapons, as well as other materiel for the Canadian Forces, is a centralized process. The process is very well defined and is based on a risk management approach and broad stakeholder engagement as well as detailed cost and value assessments through each stage of the process.

The approval authority for the purchase and deployment of the NLLD for the Canadian Forces in Afghanistan was the DND PMB. The decision was made based on advice from the Senior Review Board who conducted a detailed review of all relevant factors.

It is worth noting that the organization responsible for the overall management of the project to meet the operational requirement is the same organization that has in-service responsibility for the final equipment and in fact is responsible for the complete life cycle – cradle to grave.

2.6.5 Approval Process

The process followed by the NLLD project is typical for capital projects in National Defence and is depicted in Figure 7 below.

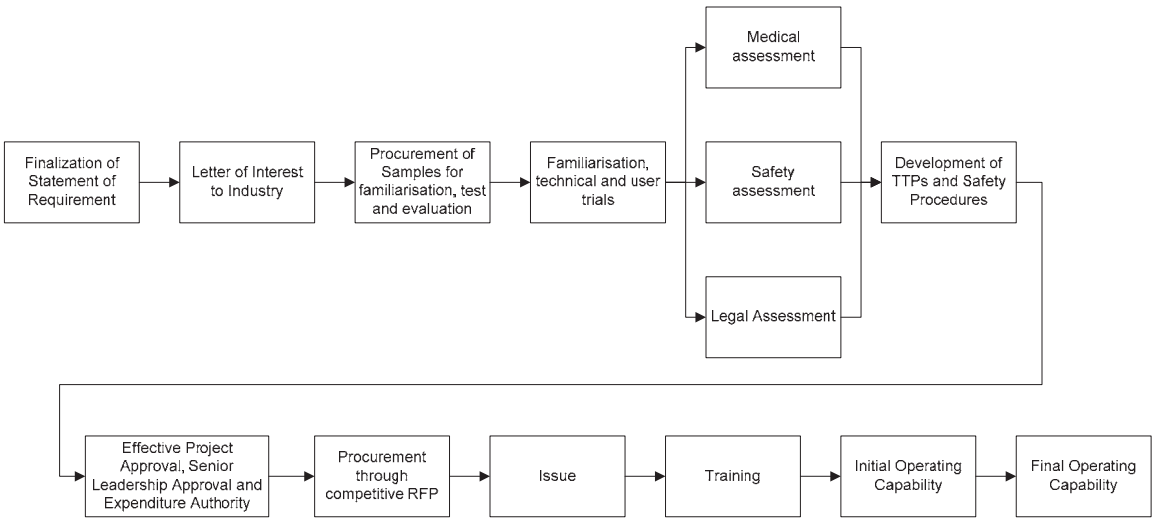

Figure 8: Non-Lethal Laser Dazzler Approval Process

The NLLD project was initiated as a result of a capability deficiency identified by the operators in Afghanistan and the requirement to fill this deficiency is formally documented by the operators in a Statement of Operational Requirement (SOR).

As an initial step, the project issued a Letter of Interest to industry to see if any products existed that could meet the SOR. This resulted in the procurement of a number of samples that underwent familiarization and user trials. All of the potential products were subjected to detailed technical assessments by DRDC Valcartier.

The project team took all of this advice as input to the Project Profile and Risk Assessment, a key document to inform the Senior Review Board of the potential risks and the planned mitigation. Section 2.6.6 outlines the nature of the risks identified. This same information was used to develop the operational tactics, techniques and procedures (TTPs) as well as any unique safety procedures required.

A complete package of all this information (Synopsis Sheet) was then presented to the Senior Review Board for endorsement before being forwarded to the DND PMB for approval. Once Expenditure Authority was received from the DND PMB, the procurement process proceeded.

In the case of the NLLD project, the requirement was met through a competitive process with input from the legal, medical, and laser safety advisors before final contract award.

The actual deployment of the devices was also staged with an initial issue and training for a smaller operational group. This allowed the team time to work out any bugs in the equipment and the TTPs before issuing the equipment to all intended users. The results of this initial deployment were presented to the SRB for formal recognition of the Initial Operational Capability (IOC) and to get endorsement to proceed to Full Operational Capability (FOC).

The project was not officially closed until the equipment was fully implemented. With the close-out of the project, responsibility for maintenance and support was handled by the in-service support organization.

2.6.6 Supporting Documentation

While there were many presentations, reports, briefing notes, etc the following documents were instrumental to the CF approval of the NLLD:

a. **Statement of Operational Requirement**. This document was a formally approved document to state the operational requirements for an effective non-lethal, active warning and deterrence capability as an alternative to deadly force. The SOR contained the following elements:[24]

   i. Climate,

   ii. Threats,

   iii. Concepts of Operations and Method of Employment,

   iv. User Characteristics,

   v. Concept of Support,

vi. Design Requirements,

vii. System Effectiveness requirements

viii. Personnel and Training Requirements, and

ix. Integrated Logistics Support.

b. **SME Assessments**. The following formal assessments were done :

x. Technical Assessment,

xi. Legal Assessment,

xii. Medical Assessment, and

xiii. Laser Safety Assessment.

c. **Project Profile and Risk Assessment**. This document provides a detailed analysis of the project risks and the consequential risks. The following consequential risks were identified and evaluated:[23]

i. Mission Success,

ii. CF Casualties,

iii. Local Casualties,

iv. Information Operations,

v. Public Affairs,

vi. Laser Safety Risk,

vii. Medical Risk, and

viii. Legal Risk.

d. **Tactics, Techniques, and Procedures (TTPs)**. The development of the TTPs is led by the Director Land Requirements (DLR), the Canadian Forces element that produces the TTPs for other army capabilities. This organization is comprised of operators. The familiarization and user trials a well as the SME assessments contribute to the development of the TTPs;

e. **Synopsis Sheet (Effective Project Approval)**. This document has a very structured format that must be followed for all capital projects. It provides all of the relevant information that must be reviewed by the SRB;

f. **Program Management Board Synopsis Sheet**. This one-page document summarizes the information needed by the PMB to approve the project and covers the Background, the Decision Required, Project Aim, and in the case of the NLLD, the Legal, Safety and Medical summary, and

g. **Initial Operational Capability** and **Full Operational Capability Certificates.** These two documents signify formal phases of the project and represent stages of rollout.

2.7 Canadian Standards Association

2.7.1 Scope

When a product is certified to a Canadian Standards Association (CSA) standard, it is recognition that the product has been evaluated through a formal process and is compliant with the requirements of a specified standard. This certification process is voluntary and is applicable to the following categories: Gas Equipment, Construction Products and Materials, Life Sciences, Electrical and Electronics, Communications and Energy. CSA certification is also recognized in the US by the Occupational Health and Safety Administration (OHSA), by the American National Standards Institute (ANSI), by National Employment Standards (NES) as well as by other regulatory authorities in Canada and the US. [25]

2.7.2 Limitations

The emphasis on the process outlined here is on receiving CSA certification. CSA also has the mandate to create national standards in Canada. There are no restrictions as to who can request the creation of a standard although requests often are initiated by consumer or trade organizations or a government department. CSA acts as neutral third party through the creation of committees drawing on a variety of expertise to develop the specifics of the proposed standard. Once a standard has been developed and has achieved consensus of the committee, input from the public is solicited before it is formally published and disseminated.

2.7.3 Stakeholders

The following stakeholders play a role in the CSA certification process:

a. The **Standards Council of Canada (SCC)** is a federal Crown corporation, reporting to the Minister of Industry, whose mandate is to promote the efficient and effective standardization in Canada. Among their responsibilities, SCC accredits standards development organizations and test and calibration laboratories in Canada.[26]

b. The **Canadian Standards Association (CSA)** is a not for profit membership-based association, with over 9000 members. Its mandate is the development of national standards for many common household products, sports equipment, devices, used in Canada. Where it makes sense, national standards are harmonized with international

or other standards. CSA is accredited by the Standards Council of Canada as one of four standards development organizations in Canada

c. **CSA International** is the division of CSA that offers their services to test products against national and international standards and to issue certification marks. [27]

d. **Manufacturers** who wish to obtain CSA certification for their products are responsible for initiating the process by identifying the standard they wish to be evaluated against and for providing detailed technical information and a sample of the product for evaluation.

e. **Accredited test organizations** may be used by the manufacturer to conduct pre-tests of the product.

2.7.4 Governance

CSA is a not-for-profit membership-based association. The decision to pursue CSA certification for any device is determined solely and independently by a manufacturer. Given that certification by CSA is not mandatory, CSA does however communicate widely to both manufacturers and the public the value of certifying products and of buying products that are CSA approved.

2.7.5 Approval Process

Figure 8 below outlines the process for obtaining CSA product certification.

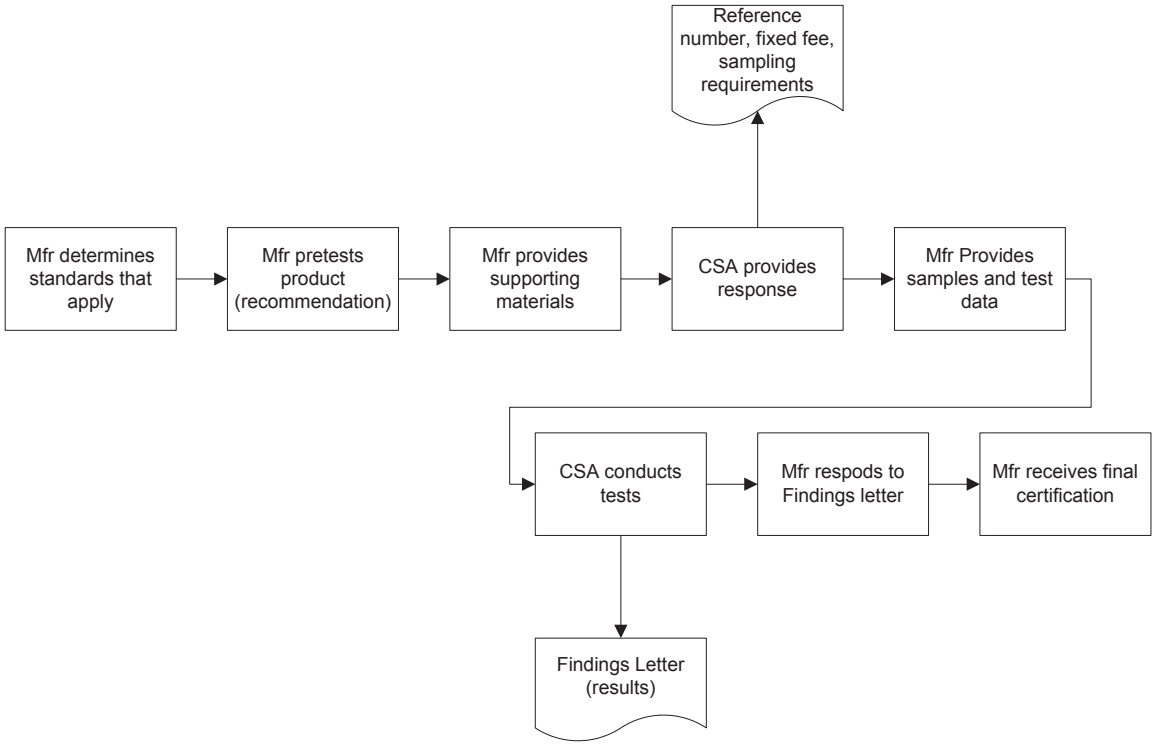

Figure 9: Canadian Standards Association Certification Process

The process is initiated by a manufacturer that would like to have their product certified to a specific national or international standard. It is up to the manufacturer in the application to CSA International to identify which standards apply. Technical advice on the application of standards is available to the manufacturer.

CSA International recommends that the manufacture conduct pre-testing of the product in order to identify any issues early that could cause delays in certification. While CSA International is available to conduct pre-tests, the manufacturer is free to do all pre-testing in house or through another accredited test organization.

As part of the formal application for consideration, the manufacturer must provide all the supporting documentation so that CSA can respond with an estimated cost, schedule and sampling requirements. Once the manufacturer provides a sample and pre-test data, they will proceed with testing and will provide the manufacturer with a findings letter that identifies any actions required.

2.7.6 Supporting Documentation

The following documentation is core to the CSA certification process:

a. CSA International requires the following documents for consideration of an **application** for CSA certification (reference):[28]

i. Marketing brochure or data sheet

ii. Photograph of the product

iii. List of all components or materials including the manufacturer's names, model, electrical rating and CSA file numbers (if applicable),

iv. Indication of any other approvals received or being pursued,

v. Any alternate materials that might be used in manufacturing,

vi. Schematic and/or wiring diagrams if electrical or electronic,

vii. Model or catalogue numbers to be covered by the certification, and

xiv. Full name and address of all manufacturing facilities

b. The **Findings** letter is produced by CSA International once the product has been tested. It documents the results of the testing and identifies any changes or actions needed to meet requirements

c. Once the product meets all of the requirements, CSA International will provide a **Certification Report** and **Certificate of Compliance**

3 Analysis of Common Elements

3.1 Governance

With the exception of the US who do not have a formal centralized process, governance for each of the approval processes is clearly identified with a single organization assigned functional authority over the process. In the case of UK LLWs, Medical Devices (Health Canada), UAVs (Transport Canada), and Telecommunications Devices (Industry Canada), the authority is vested in legislation. In the case of the approval for the use of the Non-Lethal Laser Dazzler in Afghanistan, the governance is outlined in departmental policies while the CSA accreditation process is completely voluntary and operated by a not-for-profit association.

The approval authority for each of the processes is also centralized in the functional authority organization including the UK LLWs approval process where authority for approval rests with the Secretary of the Home Office. The only deviation from the processes studied that has a centralized process is the approval of Special Flight Operations Certificates for UAV's which are approved by regional offices of Transport Canada.

For the cases where the functional authority is assigned to a Canadian federal department, the approval process may include other federal departments and agencies. The responsibility to engage these other departments rests with the functional authority.

Notwithstanding the many common elements in the LLW approval process outlined in this report, the reader should bear in mind that all approval processes are dynamic, and undergo minor adjustments and re-alignments depending upon a plethora of factors: economic, societal, technological, and governmental.

3.2 Stakeholders

The approval processes studied include a variety of stakeholders. The more structured the approval process (e.g. medical devices), the fewer stakeholders are involved, while in contrast, the less structured the approval process is, the broader is the base of stakeholders engaged (e.g. UK LLW)

As a general rule, the following groups of stakeholders play an active role in the approval process by either providing or reviewing information:

a. **Operators/End Users**: potential roles include initiating the request for approval, formulating the Statement of Operational Requirement, participating in operational trials, developing tactics and procedures for use;

b. **Functional Authority**: develops and provides oversight of the approval process;

c. **Approval Authority**: is responsible for reviewing information provided and making the final decision on approvals for operational trials and/or deployment;

d. **Manufacturers**: When they are the requesters for approval, they are responsible for providing all technical information and test results. In this case, test results must be from accredited independent laboratories. The cost of providing this information is borne by the manufacturer;

e. **Subject Matter Experts (SMEs)**: Subject matter experts provide input in their areas of expertise as advice to the approval authorities. Expertise is typically sought in the following areas: technical, medical, operational, legal, policy;

f. **Independent Review Panel**: The panel is often comprised of the Subject Matter experts. Their role is to provide advice and recommendations to the approval authority. Assembling the SMEs into a panel allows a full exchange among them.

The only process studied that engages the public is the process used by the Canadian Standards Association to develop a national standard. Once a technical standard is developed, it is posted for comments from the public however this activity is more likely to result in comments from manufacturers and technology organizations than from the ordinary citizen due to the detailed and technical nature of the standards developed. None of the processes examined indicated that they engaged input from special interest groups such as Amnesty International or Greenpeace.

3.3 High Level Process

The approval processes can be clearly identified as being end-user initiated or manufacturer initiated. The UK LLW, CF NLLD and UAVs are examples of end-user initiated approval processes, while Medical Devices, Telecommunications Devices, CSA are examples of manufacturer-initiated approval processes. Those that are initiated by the end-users are supported by operational requirements expressed as either formal stand-alone documents, or mission statements while those that are manufacturer-initiated are supported by existing technical standards.

In some cases, the complexity of the technology required the process to be broken down into different classes/categories. For example, the approval of medical devices is broken down into four classes, while telecommunication devices are divided into three classes. In a similar manner, the UAV process provides three separate approval processes depending on the category of UAV and flight planned.

Dividing the approval process into multiple classes allows for a simplified approval process for less complex devices (e.g. Class II medical devices and recreational model airplane clubs for HC and TC's processes, respectively), while requiring increased rigour for more complex devices (e.g. Class IV medical devices). This rigour includes increased requirements for independent testing as well as increased oversight/review of the application and test results.

Where formal technical standards exist, testing against these standards is done by accredited labs (e.g. medical devices, telecomm, CSA) and reviewed/validated by the approval authority. Reference is made at least by CSA and Telecomm in the use of test laboratories accredited by Standards Council of Canada or Certified to ISO/IEC 17025. The emphasis in the approval process is on the independence of testing or the oversight of testing conducted by the manufacturer.

Only the UK LLW had designed in a specific feedback mechanism to confirm the device is suitable for continued use. The medical device and UAV approval processes both had compliance mechanisms to ensure the results are as expected and to ensure the process is properly followed.

In the absence of formal technical standards, a risk management approach is taken (e.g. UK LLW and UAVs). In these circumstances, the requester is asked to conduct a comprehensive risk assessment to identify potential risks and to develop appropriate mitigation strategies. In the case of both the CF approval of NLLD and UAV's, detailed guidance is provided as the items to be considered in the risk assessment so that the review can be conducted by the approval authority.

For all of the processes, there are clearly identified subject matter expertise imbedded, with public disclosure and professional credentials provided in the case or outside expertise. In the case of the US, while they lack a formalized process, they have access to extensive technical expertise from Penn State's Technical Working Group on LLWs, NIJ, NIST and Department of Defence Joint Non Lethal Weapons Program. The UK has direct access to not only the integral Home Office CAST, but also the Ministry of Defence, Defence Science and Technology Laboratories. Their DOMILL (described in detail above) is a good example of centralization and institutionalization of independent LLW medical advice while the US has also convened an independent medical panel of outside experts. Health Canada has extensive medical expertise in-house and generally does not need to draw outside their own resources however Health Canada puts the onus on the medical device manufacturer to conduct the testing using their own resources, thereby limiting HC's activity to simply review and approve on the basis of the results. CSA draws on its broad membership for expertise and encourages the use of laboratories accredited by the Standards Council of Canada. Industry Canada takes a similar approach depending on ISO/IEC 17025 certified labs for most testing.

In summary, technical/testing support is provided through either substantial internal resources, strategic relationships with S&T organizations, or through access to accredited test organizations

3.4 Supporting Documentation

In addition to a formal application for approval, the need for supporting documentation differed among the various processes.

a. **Operational Requirement**. This document was generated by the operators and was used as the primary tool to generate the criteria for an operational trial as well as to validate that the proposed product met the requirement. (e.g., UK)

b. **Technical Standards**. Where applicable technical standards exist, they are explicitly stated in the application for approval.

c. **Agreed Guidelinesand policy for use**. This is central to the UK approach and is necessary for any informed prediction of injury potential.

d. **Risk Assessment**. This formal document outlined potential risks and presenting appropriate risk mitigation strategies.

e. **Operational Trial results**. A written report outlining the results of the operational trial is presented for review by either the approval authority or

f. **Independent Assessments** (technical, medical, legal). Various independent assessments are produced for review by the approval authority or an independent panel.

4 Recommended Elements for Canadian LLW Approval Process

4.1.1 General

This section provides a description of the building blocks that are recommended to be included in a Canadian approval process for Less Lethal Weapons. Where appropriate, and where supported by the processes studied, recommendations are made as to types of stakeholders that should participate in this activity.

The intent is for the information in this section to be presented to the Federal/Provincial/Territorial Conducted Weapons Working Group for their consideration and to help inform further discussions on the development of a Canadian approval process for Less Lethal Weapons. Nothing that is stated here should be taken to be all-inclusive or prescriptive as the recommendations provided here do not represent all perspectives.

4.1.2 Guiding Principles

The following principles are recommend to guide the development of the Canadian LLW approval process:

a. **Transparency** – the approval process needs to be seen as transparent by the Canadian public in order to engender public confidence

b. **Independent** – the approval process needs to be independent of undue influence from product manufacturers

c. **Flexibility** – the approval process needs to be flexible enough that steps/requirements can be added or deleted as the need may justify with sufficient off-ramps built in

d. **Operationally relevant** – the approval process needs to consider the operational requirements of the end user in order to ensure effective and efficient approval

e. **Inclusive** – that Canadians are afforded the opportunity to participate and submit public input and review into new LLW approval processes,

4.1.3 Governance

While it would appear that the UK LLW weapon approval process is a potential model for Canada to consider, the governance model for law enforcement in the UK is significantly different from that for law enforcement in Canada. In Canada, provinces and territories are responsible for the administration of justice in their jurisdiction, including providing direction on the use of all types of force by police. Previous work related to the employment and testing of Conducted Energy Weapons, under the leadership of Public Safety Canada, has focused on developing consensus with the provincial and territorial stakeholders to endorse common

guidelines. These guidelines have been developed based on national consultations and may be considered by provinces and territories as well as police services and other agencies in Canada in the development of their individual policies and procedures for CEWs. These guidelines reflect areas to be addressed in detailed policies (e.g., use, training, testing, supervision and reporting, recognizing that jurisdictions may align some or all elements of their own policies or procedures with these guidelines).

None of the models reviewed in this study had a decentralized functional authority. The closest model is the Transport Canada approval of UAVs. In this situation, although the approval is decentralized (still part of Transport Canada), the Staff Instruction to ensure consistency of approach is provided by the federal department and must be followed by all Transport Canada employees.

While it is recommended that the approval authority be decentralized, the use of different approval processes for each FPT could potentially result in policy inconsistencies and duplication of resources. A systematic approach to the approval of LLWs requires significant resources and there is much to be gained by sharing methods and results where feasible. It is highly recommended that, where practical, an economy of effort be achieved through formalized information sharing and cooperative activities. For example, it would be helpful if the results of a legal analysis or operational trial could be shared by stakeholders.

All of the processes studied had a clearly identified functional authority including the UK. In the case of a Canadian LLW approval process, a centralized functional authority would be difficult given the present law enforcement governance structure; however the effect of a centralized functional authority could be achieved through the use of a formal committee with representation from each of the provinces and territories. This organization could serve as the formal mechanism to share information, Subject Matter Expert assessments, operational policies, training guides and operational trial results.

4.1.4 Risk Management Approach

Few of the LLWs being considered for use by law enforcement have technical standards that could be used to accept or reject the device. In addition, the complexity of the use of less lethal weapons in an operational context requires a much broader risk management approach be taken. This will allow a wider variety of factors to be considered and would encourage the engagement of more stakeholders. This is the approach followed by the UK and by the CF in approving less lethal weapons. As a minimum, the following risks are recommended for evaluation:

a. **Risk of injury to law enforcement**. Consider the risk with the proposed device vs. without the proposed device. The thinking should encompass short term and long term horizons;

b. **Risk of injury to subject or bystanders**. Consider the risk with the proposed device and without the proposed device;

c. **Public Affairs/public perception**. How is the use of the device expected to be perceived in the eyes of the public either through direct observation or through the media?

d. **Legal Risk**. Consider the legal context under which the device can and cannot be used. How does this affect the intended mission? This risk element has the most influence on the development of tactics and operational procedures governing use of the proposed device;

e. **Life Cycle Costs**. Consider not only the purchase cost, but also the cost of consumable supplies, maintenance and disposal.

f. **Operational Policies and Procedures**. Where does this device fit in the Use of Force Process? What new skills are required to operate it? What changes in training will be required? Does it fit within current law enforcement tactics? What policy changes would be needed?

g. **Scientific and Technical**. What is the maturity of the device? Is it likely to undergo multiple versions or is it a stable product? Has independent testing been done and are the results available? Is there a complete understanding on how the device operations and potential areas of technical failure?

h. **Interoperability**. Does the use of this device impact on the ability of law enforcement to be interoperable with other first responders including other law enforcement agencies? Is it interoperable with other existing devices/equipment including personal protective gear?

4.1.5 Statement of Operational Requirement

The request to approve a specific less lethal weapon for use in Canada will most likely be initiated by a law enforcement agency as opposed to a manufacturer; therefore the Statement of Operational Requirement (SOR) is a key document. It is recommended that this document be created by the operators or by an agency that speaks on behalf of the operators. In the UK, this is the ACPO while for the CF laser dazzler; it was the Director of Land Requirements.

For Canadian law enforcement, the equivalent of the ACPO is the Canadian Association of Chiefs of Police (CACP). This is a non-profit association, comprised of approximately 1000 members, "dedicated to the support and promotion of efficient law enforcement and to the protection and security of the people of Canada." [30]

The SOR is intended to essentially answer the following questions: What do you need? What do you need it to do? And how do you need to use it? It is recommended that this document be developed in advance of consideration of any specific product make or model in order to not influence the operational requirement and potentially miss critical requirements. The SOR should never specify "which one."

The recommendation is for the SOR to be submitted by the operators as an initial step in the approval process for a less lethal weapon. This document will be referred to frequently throughout the process to ensure that each step of the process has adequately addressed the needs of the operators. It is reasonable for the SOR to be a living document and to be updated as additional information becomes available however it is critical that the content of the SOR represent the needs of the operational community and not be changed to reflect preferences of

policy makers. In the circumstances where there are multiple capabilities required, then multiple SORs would be needed. For example, the SOR to purchase a capability to disperse a crowd would not be the same as an SOR for the capability to restrain an individual.

SORs should outline both mandatory requirements and desirable requirements. Devices that do not meet mandatory requirements are deemed unsuitable while desirable requirements indicate a value-added operational contribution. In phrasing requirements, mandatory requirements typically use the following words: 'must', 'shall', 'will' while desirable requirements typically use the word 'should'.

Ideally, an SOR should contain the following information:

a. **Aim and Objectives**. The SOR should contain a statement in clear terms that outlines the scope of this requirement;

b. **Background**. This section should explain the circumstances that have resulted in the need for an operational requirement;

c. **Capability Deficiency**. In operational terms, describe what is wrong with the status quo. Explain what workarounds are in place to achieve the end state and why these alternatives are not acceptable;

d. **Concept of Operation**. This section should describe in detail how the proposed device would fit into the current tactics and procedures. It should include a description of the applicable scenarios this device could be used in and how it would fit in the National Use of Force Framework (NUFF). This section should be substantive as it gives a good indication of how the device is proposed to be used. This section should also explain who the typical user is expected to be and what quantities of devices are being considered or would be needed to meeting the objectives;

e. **Concept of Support**. This section should describe how the devices would be supported. In the case of law enforcement, there is limited maintenance and support capability therefore the expectation is that the manufacturer would need to provide support for anything beyond user maintenance;

f. **Design**. This section should include details on the physical characteristics of the device and how it would interact with the end user. Some of the things to consider include:

    i. Size, weight, shape

    ii. Usability of controls and switches,

    iii. Interaction with personal protective equipment (PPE),

    iv. Operator safety,

v. Visual/auditory recognition by other law enforcement, subject and bystanders, and

vi. Interoperability with other law enforcement equipment (e.g. Vehicles)

g. **System Effectiveness**. These requirements relate to the performance characteristics of the device that are needed to achieve the objective. Some of the items to consider include:

i. Operating distance and duration (in various climate, time of day conditions),

ii. Aiming and firing accuracy and precision including the conditions under which it would be operated (e.g. running)

iii. Speed of access and operation including repeated application,

iv. Reliability in various circumstances such as after being exposed to water, dropping, high volume use,

v. Durability including how long it should remain in service, its requirement to withstand harsh environments without performance degradation,

h. **Tactics, Techniques and Procedures**. If the desired device must fit within existing tactics, these should be identified as references. If new tactics will be needed, this should be stated.

i. **Personnel**. The SOR should identify the role of the intended user by job function if possible as well as any special training this person would be expected to have. If there are additional personnel that would need to be added to either operate or support the device, it needs to be stated.

j. **Training**. Does this device fit into existing training or would new or specialized training be required? Can this training be conducted by existing organizations or is an alternate source required?

One of the key roles played by the SOR is to evaluate potential products during an operational trial. The operational trial should factor in the requirements identified in the SOR and be designed to explicitly evaluate the ability of the proposed devices to meet the operational requirements. The SOR would also be used to guide any new policies that will be needed as a result of the introduction of the new device.

4.1.6 Independent Assessments

In the case of LLWs, there is no expectation that the approval authority will have all the information required to make an informed decision. By conducting an assessment independent of the manufacturer, the approval authority can be confident that the advice being provided is as free of bias as possible. It should be noted that these assessments are as advice to the approval authority only and are not deemed to be approvals in themselves.

There are a variety of areas that could have independent assessments, but the following are the areas where enlisting subject matter expertise is recommended:

4.1.6.1 Technical

The most difficult area related to LLW to understand is the technical functioning of the device. Neither police services nor policy makers will have the technical expertise to adequately assess technical and performance claims made by the manufacturer. In the case of the UK LLWs, the HOCAST provides the technical assessment in cooperation with the DSTL. Similarly, the NIJ in the US provides in-depth and independent technical assessments for law enforcement. In the case of the telecommunications devices and medical devices, this assessment is done by independent accredited test laboratories and the results are provided to the technical authority.

For Canadian LLWs, DRDC CSS has a mandate similar to NIJ to provide technical advice and support to law enforcement agencies. In particular, the Canadian Police Research Centre program provides funding to address science and technology gaps identified as priorities by the first responder communities. If DRDC CSS does not have the required expertise in-house, they have the ability to obtain access to the expertise from the rest of DRDC (as was the case for the CF NLLD), industry or academia. Access to these resources would require identification of the deficiency as a priority gap.

Support for conducting a technical assessment can also be provided locally by research and development companies or universities under contract to the approval authority although it is recommended to use accredited test laboratories. Another valid option for obtaining a technical assessment of devices is to exchange information with both NIJ and CAST under memorandums of understanding that Canada has with the US and the UK. This would reduce the need to conduct duplicate assessments and would allow a quicker turnaround to the approval authority.

The technical assessment should be done on all devices being considered. As a minimum, this technical assessment should include a full characterization of the device and validation of manufacturer claims of performance. Where technical standards exist, the technical assessment should verify the device meets the technical standard. This evaluation should be conducted in a test laboratory to eliminate any outside factors. The results of this technical assessment should be used to guide the development of tactics and safety guidelines. It is recommended that the technical SME be included in any evaluation of vendor proposals where selection is based on technical criteria.

In some circumstances, devices may be eliminated from further consideration based on the results of the technical evaluation.

4.1.6.2 Medical

The nature of LLWs is such that there is no guarantee against injury or death. Because of this, law enforcement must be fully informed of the risk of injury or death to not only the subject, but also any bystanders and law enforcement personnel. It is recommended that the medical assessment be conducted based on information provided by the manufacturer, but that the medical assessment not be finalized until the technical assessment is complete. This order is preferred in

order to facilitate the exchange of information between the medical and technical assessment teams. The medical team may identify specific areas of concern to be validated by the technical team, while the technical results may identify specific areas for medical consideration.

In the case of the approval of medical devices and the CF NLLD, the medical expertise was provided in-house. In the case of the Canadian LLW approval process it is recommended that the medical expertise to conduct the formal medical assessment be sought within the approval authority's organization because of issues of accountability and attribution of advice. In the circumstances where the in-house medical staff does not have sufficient expertise in the appropriate areas, a panel of the appropriate experts may be needed to gain the full perspective. Engaging a broad selection of experts in the medical field will minimize the risks. The most comprehensive model for independent medical advice found is that of the DOMILL (described in detail above in UK approval process section); this body encompasses many of the features below to ensure a totality of independent and comprehensive medical evaluation.

The medical assessment should identify the following elements:

a. Permanently appointed, multi-disciplinary team approach to LLW medical risks/implications

b. Flexible membership, including new medical disciplines where the need arises

c. Immediate physical/physiological effect on the subject and likelihood it will achieve the desired result,

d. Immediate medical/physiological effect on the subject and the likelihood of pain, injury, or death,

e. Long term physiological or medical effects on the subject,

f. Impact of repeated application on short and long term physiological effects on the subject,

g. Short and long term physiological/medical effects on bystanders and law enforcement personnel,

h. Psychological effect on subject (short and long-term),

i. Any contraindications to use on at risk populations,

j. Recommended follow-up care to subject or bystanders, and

k. Recommendations for any specific safety thresholds that should be included in tactics and procedures.

l. Membership of an impartial government representative to serve as linkage to governance process

Areas where the medical impact cannot be determined should be clearly identified as areas requiring additional research and development.

4.1.6.3 Operational

The operational assessment is formally conducted through the conduct of an operational trial which is discussed further in Section 4.1.8. As was stated in section 4.1.5, the Statement of Operational Requirement is the formal mechanism by which the operational expertise is communicated to the approval authority. The approval authority needs access to operational expertise throughout the approval process for advice and clarification of issues that have operational impact. This role is often practically filled by the police service requesting approval of the device.

4.1.6.4 Legal

Because of the legal implications of both the approval and the deployment of a LLW, the decision to approve should not be taken without a formal legal opinion. It is recommended that this opinion be sought from legal advisors responsible for advising the approval authority's organization to ensure the perspective is from the approval authority.

4.1.6.5 Public Affairs

While not critical to the approval decision, engagement of public affairs personnel in the approval process will ensure that the role, function and the results of SME assessments is properly communicated to the public. This will avoid any misinformation that can quickly erode public trust.

4.1.6.6 SME Panel

Once the assessments are completed, it is recommended that the approval authority convene a panel to review the results of the SME assessments. This will allow for a professional exchange and discussion on the risks based on the assessments of each SME. This is the best mechanism for the approval authority to get a complete picture and to make the most informed decision.

4.1.7 Development of Tactics and Procedures

The development of tactics and procedures must be done prior to any operational trial and is best tackled with the full knowledge of the SME assessments. There are circumstances where tactics will need to be changed to adapt to a new technology and these need to be developed so that they can be validated during an operational trial and so that any impact on training can be properly assessed. This work is best undertaken by policy, standards or training personnel with input from the operator community.

4.1.8 Operational Trial

The main objective of an operational test or trial is to validate that the proposed device satisfies the needs as expressed in the SOR and to confirm it is suitable for the intended use. It is important to determine whether the trial is to be conducted using a volunteer police force, or to a semi-realistic trial that does not involve actual deployment of the LLW. Both versions are necessary but measure different outcomes. The operational trial functions as an important risk mitigation measure before a device is introduced into service and provides a final opportunity to validate the proposed tactics and procedures, the technical support plan and any other operational issues as well as confirming that the device will do what they think it will do. The results of this operational trial will constitute the final advice provided to the approval authority.

An operational trial is best led by an organization or team that is independent of the manufacturer and also of the intended end user. [31] The lead of the operational trial is responsible for building the evaluation plan, coordinating the resources, executing the plan, collecting data according to the plan and preparing the written report. The skills found in training organizations/teams are well suited to leading an operational trial. They have a good understanding of the operational environment and have experience in developing scenarios for training that will be valuable to reuse in an operational trial.

It is important that an operational trial only use production versions of the proposed device – experimental or prototype version of LLWs are not suitable for an operational trial in support of a LLW approval process because they may not adequately represent the performance and behaviour of the final production model.

The operational trial should be conducted under conditions that as closely as possible represent the operational environment. This includes variables such as weather, time of day, etc. The trial should also be developed around realistic scenarios. Scenarios are used to frame an operational trial for the purpose of observing the performance of the device under a range of circumstances and are comprised of context, participants, environment and evolution of events in time. [32] Participants in the trial need to be typical end users that are trained to the same level as the expected end user.

Collection of data during the trial is critical to supporting the decision for use. Data collected can be objective through observation by independent analysts or through physical measurement (e.g. measuring the time to complete a task such as deploying the device or the distance at which the device operates) or the data collected can be subjective through the use of questionnaires or interviews. Any technical issues noted with the equipment should be noted and reported along with any actions taken or workarounds used.

The results of the operational trial need to be presented in a formal report that will be taken into consideration by the approval authority. The results of this operational trial can also be used by other law enforcement agencies considering a new LLW.

4.1.9 Feedback/Validation

It is not enough to simply begin using a LLW once it has been approved. There is a requirement to confirm the device both continues to function technically, confirm that the risks that were

assumed are indeed real values on humans (officers, suspects, bystanders), but also that it continues to be the proper tool for the job. There are a number of mechanisms available to implement a feedback loop or validation mechanism:

a. **Targeted Study**. A formal study could be scheduled at specified period of time following implementation into use by law enforcement. This study should be conducted by an organization independent of the end users and could involve issuing surveys/questionnaires to collect subjective information on the effectiveness of the device. The study could also involve a review of situations where the device was used. This would require all users to report usage information in a consistent manner.

b. **Continuous Reporting**. A mechanism could be implemented that requires any technical or functional issues to be reported to an identified organization that would be able to identify any systemic problems with technical performance, training or tactics and procedures.

c. **Continuous Monitoring**. As endorsed by the NIJ, a third party group, imbedded within the police, could be made available to sample and review incidents on a national basis. They would monitor changes in risk and estimate the reason for the change and provide reccomendations to lower this risk. If the risk decreases, they could evaluate the reason for this reduced risk, and report this to other agencies for incorporation. This could be also applicable to improving tactics. This group could also be more focused on LLW's recently approved to verify that the estimated risk is indeed the actual risk to humans.

The decision to obtain feedback/validation after implementation needs to be made at the time of approval because of the requirement to put personnel and financial resources in place and to establish reporting protocols.

5 Conclusion

This study was initiated to address one of the elements of the CEWSI project – the need for an approval process for LLW for Canadian law enforcement. This report presents the result of the study undertaken by a contractor of a variety of technology approval processes. The following approval processes were explored: US LLW, UK LLW, CF NLLD, HC medical devices, TC UAVs, IC telecommunications devices, and CSA certification. For each of the processes reviewed, the following elements were looked at in detail: Scope, Limitations and Restrictions, Stakeholders, Governance, High Level Process elements and Supporting Documentation.

An analysis of the various approval processes was then conducted to identify common elements. There was commonality in the assignment of functional and approval authorities, the categories of stakeholders that were engaged, the use of classification systems to decompose complex technology areas, the use of accredited test and technology organizations, access to subject matter expertise (technical and medical), and the use of a risk management approach in the absence of formal technical standards.

The final aspect of this report presents recommended building blocks that could be applied to a LLW approval process for Canadian law enforcement. Recommendations were made in the area of Governance, Risk Management, Statement of Operational Requirement, Independent Assessments, Development of Policies and Procedures, Operational Trials and Validation/Feedback.

The results of this study will inform the FPT CEW WG on what would be needed in a LLW approval process in Canada.

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List of symbols/abbreviations/acronyms/initialisms

ACPO	Association of Chief Police Officers
AMA	Academy of Model Aeronautics
ANSI	American National Standards Institute
BETS	Broadcasting Equipment Technical Standards
CACP	Canadian Association of Chiefs of Police
CAR	Canadian Aviation Regulations
CB	Certification Body
CEB	Certification Engineering Bureau
CEW	Conducted Energy Weapons
CEWSI	Conducted Energy Weapons Strategic Initiative
CF	Canadian Forces
CISPR	Comité International Spécial des Perturbations Radioélectriques
CNSC	Canadian Nuclear Safety Commission
COTS	Commercial Off The Shelf
CPRC	Canadian Police Research Centre
CSA	Canadian Standards Association
CSS	Centre for Security Science
DFAIT	Department of Foreign Affairs and International Trade
DGLEPM	Director General Land Equipment Program Management
DLR	Directorate Land Requirements
DND	Department of National Defence
DOC	Declaration of Conformity
DoD	Department of Defence
DOMILL	DSAC Sub-Committee on the Medical Implications on Less Lethal Weapons
DRDC	Defence Research & Development Canada
DRDKIM	Director Research and Development Knowledge and Information Management
DSAC	Defence Scientific Advisory Council
DSTL	Defence Science and Technology Laboratory
FBP	Federal Bureau of Prisons

FOC	Full Operational Capability
FPT	Federal/Provincial/Territorial
HC	Health Canada
HO	Home Office
CAST	Home Office Centre for Applied Science and Technology
HPFBI	Health Products and Food Branch Inspectorate
IC	Industry Canada
ICES	Interference Causing Equipment Standards
IEC	International Electro-technical Commission
ILEF	International Law Enforcement Forum
IOC	Initial Operational Capability
ISO	International Standards Organization
ITU	International Telecommunications Union
JNLWP	Joint Non-Lethal Weapons Program
LLW	Less Lethal Weapons
MAAC	Model Aeronautics Association of Canada
MDB	Medical Devices Branch
MDP	Medical Devices Program
MHPD	Marketed Health Products Directorate
MoD	Ministry of Defence
MRA	Mutual Recognition Agreement/Arrangement
NES	National Employment Standards
NIJ	National Institute of Justice
NIST	National Institute of Standards and Technology
NLLD	Non-Lethal Laser Dazzler
NPIA	National Policing Improvement Agency
OHSA	Occupational Health and Safety Administration
OR	Operational Requirement
R&D	Research & Development
RABC	Radio Advisory Board of Canada
RCMP	Royal Canadian Mounted Police
REL	Radio Equipment List

RSS	Radio Standards Specification
S&T	Science and Technology
SCC	Standards Council of Canada
SFOC	Special Flight Operations Certificate
SME	Subject Matter Expert
SOR	Statement of Operational Requirement
SRB	Senior Review Board
TAPAC	Terminal Attachment Program Advisory Committee
TC	Transport Canada
TEL	Terminal Equipment List
TM	Technical Memorandum
TPD	Therapeutic Products Directorate
TTPs	Tactics, Techniques and Procedures
UAV	Unmanned Aerial Vehicles
UK	United Kingdom
UN	United Nations
US	United States
WG	Working Group

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DOCUMENT CONTROL DATA

(Security classification of title, body of abstract and indexing annotation must be entered when the overall document is classified)

1. ORIGINATOR (The name and address of the organization preparing the document. Organizations for whom the document was prepared, e.g. Centre sponsoring a contractor's report, or tasking agency, are entered in section 8.)

Centre for Security Science (CRTI/PSTP)
Defence R&D Canada
222 Nepean St. 11th Floor
Ottawa, ON Canada K1A 0K2

2. SECURITY CLASSIFICATION (Overall security classification of the document including special warning terms if applicable.)

UNCLASSIFIED

3. TITLE (The complete document title as indicated on the title page. Its classification should be indicated by the appropriate abbreviation (S, C or U) in parentheses after the title.)

Toward the Development of a Canadian Less Lethal Weapon Approval Process:
A Study of Contemporary Process Models

4. AUTHORS (last name, followed by initials – ranks, titles, etc. not to be used)

Goodman. L; Wood, D

5. DATE OF PUBLICATION (Month and year of publication of document.)

October 2011

6a. NO. OF PAGES (Total containing information, including Annexes, Appendices, etc.)

73

6b. NO. OF REFS (Total cited in document.)

31

7. DESCRIPTIVE NOTES (The category of the document, e.g. technical report, technical note or memorandum. If appropriate, enter the type of report, e.g. interim, progress, summary, annual or final. Give the inclusive dates when a specific reporting period is covered.)

Technical Memorandum

8. SPONSORING ACTIVITY (The name of the department project office or laboratory sponsoring the research and development – include address.)

Centre for Security Science
Defence R&D Canada
222 Nepean St. 11th Floor
Ottawa, ON Canada K1A 0K2

9a. PROJECT OR GRANT NO. (If appropriate, the applicable research and development project or grant number under which the document was written. Please specify whether project or grant.)

32bj

9b. CONTRACT NO. (If appropriate, the applicable number under which the document was written.)

10a. ORIGINATOR'S DOCUMENT NUMBER (The official document number by which the document is identified by the originating activity. This number must be unique to this document.)

DRDC CSS TM 2011-17

10b. OTHER DOCUMENT NO(s). (Any other numbers which may be assigned this document either by the originator or by the sponsor.)

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One of the objectives of the Conducted Energy Weapons Strategic Initiative (CEWSI) project is to develop a Canadian approval process that could be applied to emerging less lethal technologies. A contract was let with Alcea Technologies to survey a variety of approval processes with the objective of identifying common elements that could be applied to the Canadian less lethal weapons approval process.

The contractor identified the stakeholders, roles and responsibilities, governance framework, high level processes and supporting documentation for the Less Lethal Weapons Approval Process used by the United States and the United Kingdom as well as for the following Canadian approval processes: Medical Devices, Telecommunications Devices, Unmanned Aerial Vehicles, CSA approval and the use of the Laser-Dazzler by the Canadian Forces in Afghanistan.

This report presents the findings of the contractor's work, identifies the common elements among the processes and recommends building blocks that should be included in a Canadian less lethal weapons approval process.

L'un des objectifs de l'Initiative stratégique sur les armes à impulsions (ISAI) est d'élaborer un processus d'approbation canadien qui peut être appliqué aux nouvelles technologies dans le domaine de la létalité atténuée. Un contrat a été adjugé à Alcea Technologies afin que cette entreprise passe en revue divers processus d'approbation et ce, dans le but de répertorier les éléments communs qui pourraient être appliqués au processus d'approbation canadien relatifs aux armes à létalité atténuée.

L'entrepreneur a fait l'inventaire des intervenants, des rôles et responsabilités, du cadre de gouvernance, des processus de haut niveau et des documents pertinents utilisés dans le cadre des processus d'approbation des armes à létalité atténuée en vigueur aux États-Unis et au Royaume-Uni. De plus, l'entrepreneur a recensé les différents processus d'approbation canadiens liés au matériel médical, aux appareils de télécommunication, aux véhicules aériens sans pilote, à l'homologation de l'ACNOR et à l'utilisation du dispositif d'aveuglement Laser Dazzler par les Forces canadiennes en Afghanistan.

Ce rapport présente les résultats des recherches de l'entrepreneur, il répertorie les éléments communs parmi les différents processus et fait des recommandations concernant les étapes qui devraient être suivies dans un processus d'approbation des armes à létalité atténuée.

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Less Lethal Weapons; Conducted Energy Weapons