2005 ANNUAL REPORT

OF

THE BIOLOGICAL AND CHEMICAL DEFENCE

REVIEW COMMITTEE

THE COMMITTEE

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INTRODUCTION

The policy of the government of Canada is to press for global, comprehensive and verifiable treaties to ban all biological and chemical weapons. Even so, the threat from such weapons persists. Accordingly, Canada has an obligation to ensure that members of the Canadian Forces (CF) have adequate training and equipment to protect themselves against exposure to chemical and biological agents. This protection is required for deployments on foreign soil and, as the threat of terrorist action exists in Canada, it is also required for any military response to domestic emergencies.

The Canadian public has the right to be assured that Canada's policy of maintaining only a defensive capability in this field is fully respected at all times, and that any research, development and training activities undertaken pose no threat to public safety or the environment.

To facilitate this assurance, the Biological and Chemical Defence Review Committee (BCDRC) was established by the Minister of National Defence. The Committee is mandated to review annually the research, development and training activities in biological and chemical defence (BCD) undertaken by the Department of National Defence (DND) to ensure that they are defensive in nature and conducted in a professional manner with no threat to public safety or the environment.

Committee members are recommended by learned Canadian scientific societies and chosen by the Chairperson. The BCDRC is usually comprised of a chairperson and at least two members representing disciplines relevant to BCD such as chemistry, microbiology and toxicology. The Chairperson is appointed for a term of five years by the Deputy Minister of Defence (DM) and the Chief of the Defence Staff (CDS) from amongst the existing Committee members. The present members are:

Chair	Chair Dr. Kenneth L. Roy	University of Alberta [Microbiology]		
and				
Member	Dr. Colin R. McArthur	York University [Chemistry]		

The Committee is short one member because the federal system for establishing security clearances is currently swamped with applications. The BCDRC is awaiting the security clearances for two new members.

Commencing in 1990, Annual Reports have been submitted. All have been made available to the public and are reproduced on the BCDRC Internet web page (<u>www.vcds.dnd.ca/bcdrc/index.html</u>). The reports use many military and government abbreviations. The abbreviations are used only after the full terms they represent are spelled out at least once. However, to make the reports easier for the reader, the abbreviations are summarized in Annex C which is a separate page on the web site.

SUMMARY

This report records the 2005 year activities of the BCDRC. Included in annexes are the Committee's review of the current state of the implementation of the recommendations made in the 1988 Barton Report and the progress made on the implementation of recommendations made in previous BCDRC reports. The BCDRC was itself organized as the result of a recommendation in the Barton Report. The Barton Report may be read on the BCDRC Internet web page.

The BCDRC has concluded that there are neither indications of duplicity within Canada's BCD program nor evidence that offence related activities are being conducted either on behalf of Canadian authorities or to comply with any multilateral treaty commitment.

During the 2005 visits, the BCDRC received briefings about the collision of a courier van with another vehicle in Winnipeg. The van was carrying vials of anthrax. The Committee believes that the Canadian public was not put at risk by the collision.

In 2005, the BCDRC has received more information about the possible shortage of suitable laboratory space for research into defences against biological agents. This type of research requires Level III Containment laboratories (see Annex C for a definition of Level III Containment). In 2004, the Committee made a recommendation that a balance be kept among numbers of research scientists and the numbers of laboratories and amounts of equipment they require for research. That is, the Committee has already recommended that suitable facilities for research, including Level III Containment laboratories, be maintained.

During 2005, the Committee witnessed some excellent demonstrations of decontamination of soldiers and equipment. The BCDRC recommends that the CF maintain its expertise in this important field.

COMMITTEE ACTIVITIES - - 2005

During 2005, the BCDRC made its annual visits to DND establishments involved in the BCD program. These establishments included:

National Defence Headquarters (NDHQ) with briefings from or meetings with: Defence R&D Canada (DRDC) Corporate Centre, including meetings with the Assistant Deputy Minister (Science and Technology) and the acting director of the Chemical, Biological, Radiological/Nuclear Research and Technology Initiative (CRTI), a federal government program led by DRDC; Directorate Nuclear, Biological and Chemical Defence (DNBCD) including a meeting with the director; Directorate Arms Proliferation Control Policy (DAPC Pol) including a meeting with the acting director; and

Director General of Health Services (DGHS): Canadian Forces Medical Group/Operational Medicine (CFMG Op Med);

Land Forces Western Area (LFWA) Headquarters and 1 Canadian Mechanized Brigade Group (1 CMBG) (Edmonton, Alberta), including meetings with the Commanders;

The Joint NBC Defence Company (JNBCD Coy) (Trenton, Ontario) with briefings about its start-up and current activities;

Canadian Forces Support Training Group (Borden, Ontario) including a meeting with the acting commander;

Canadian Forces Nuclear, Biological and Chemical School (CFNBCS) (Borden, Ontario) with briefings about its responsibilities, resources and training; DRDC Toronto with an overview briefing and a briefing about the DRDC Human Research Ethics Committee; and

DRDC Suffield (Alberta) with briefings about the responsibilities, resources and activities of the research establishment and the BCD program. The Committee also heard plans for developing the Counter Terrorism Technology Centre (CTTC) at Suffield and was briefed on the CRTI in which Suffield participates. The Committee toured the facilities and met with scientists from several research groups in the establishment. Time was made available to allow any member or groups of members to approach the Committee to discuss matters of concern. While at DRDC Suffield, the BCDRC met with the director general, the deputy director general/head of CTTC, the head of the BCD program and other members of the senior staff. The Committee held discussions with the General Safety Officer and the Environmental Safety Officer.

Outside of DND, the BCDRC met with officers in Foreign Affairs Canada to discuss the Chemical Weapons Convention (CWC) and the Biological and Toxins Weapons Convention (BTWC) and Canada's participation in them.

In June, Dr. McArthur attended a seminar about CRTI projects and in November, visited scientists conducting work on a chemical degradation project at Royal Military College, Kingston, Ontario. In December, the Committee members attended a DNBCD workshop in Cornwall, Ontario.

The BCDRC reviewed DND's 2005 BCD Research and Development (R&D) Program and determined that it was in accordance with current Canadian Government policy. The latest version of the DRDC Service Level Agreement (SLA) for BCD and current R&D contracts and publications lists were examined. In addition, the DRDC accountability documents were scrutinized.

To enhance our perspective of the concerns of Canadians in Canada's BCD activities, the Committee invites any group of concerned citizens to meet and discuss issues. The Committee met with author and former MP John Bryden, author and historian Dr. Donald Avery and toxicologist Dr. Heather Durham, a former chair of the BCDRC. The Committee has been contacted for information by other organizations and individuals during the year. Any group or individual that wishes to make representation to the Committee should contact the executive officer. Contact information is found in the Introduction section of the web site.

In the past, during meetings with groups of concerned citizens and of the media, some concerns about DND's BCD program have been identified and reasoned responses were given by the Committee at those times. These comments were repeated in the BCDRC annual report until 2001 (the 2001 and earlier reports are available on this web site). Please refer to these reports for explanations of the difference between offensive and defensive biological and chemical research and means of obtaining information about BCD from DND.

DISCUSSION

The members of the BCDRC wish to thank all the organizations visited for their hospitality during 2005. They wish to thank in particular the Commanders of 1 CMBG and LFWA. Sometimes an organization that is not on the Committee's annual visit cycle is reluctant to be totally open with the BCDRC. The Land Forces in Edmonton packed as much activity and information as possible into the Committee's short visit. The Committee's impression was that LFWA had a higher level of awareness of BCD than had been encountered during previous visits to the Army.

On 2 March, 2005, a courier van in Winnipeg was involved in a collision with another vehicle while carrying a package shipped from DRDC Suffield to Health Canada's National Microbiology Laboratories (NML). The shipment contained vials holding small samples of 11 strains of anthrax. The shipment was packed in approved crash-proof containers and was not damaged. The package was delivered to NML mid morning on 2 March. The BCDRC has been aware that shipments of biological agents occur in Canada and in its 2002 report recommended that Defence R&D Canada (DRDC) prepare guidelines for the transfer of chemical and biological agents and toxins to civilian facilities and their subsequent use at the civilian facility. The Committee is satisfied that, when shipping agents, DRDC Suffield complies with the Transport of Dangerous Goods Act supervised by Transport Canada. In the Winnipeg case, the shipment was approved by the Canadian Food Inspection Agency Biohazard Containment and Safety Division and the Public Health Agency of Canada, Office of Laboratory Security, Centre for Emergency Preparedness and Response. The appropriate Material Transfer Agreement, developed as a result of the BCDRC recommendation, was signed between NML and DRDC Suffield.

The BCDRC considered whether the procedures for the transfer of such goods were sufficient to protect the Canadian public. The Committee was satisfied that containers for the shipment of biological and chemical agents are sufficiently strong to withstand any collision or upset. The samples in this case were triple-packed in containers designed to survive a drop from the tenth floor of a building. The Committee also questioned whether a private courier company is suitable for such shipments. The alternative might be to use government vehicles with a police escort. The Committee is satisfied that the anonymity provided by using private carriers provides a good degree of security and use of public vehicles and escorts would be costly and would draw unnecessary attention to the shipment.

The BCDRC received briefings about DND projects aimed at cleaning up sites in Canada which may be contaminated by chemical and biological waste resulting from military R&D. The Warfare Agent Disposal (WAD) project is investigating sites across Canada where contamination resulting from, mostly, wartime research may still exist. The group conducting this study was due to complete a historical review in May 2005 and a scientific review and assessment in December 2005. Recommendations for remediation of the sites will follow those reports. A second project is investigating contaminated sites within the boundaries of the DRDC facility at Suffield, Alberta where much of Canada's research and development of chemical and biological warfare agents occurred. In Suffield, nine sites were being investigated. During the study of these locations, it was determined that at least some of them had been used as dumps for unused canisters and mortar shells containing riot control and more dangerous chemical agents. The work in Suffield has been halted and all nine have been declared high-risk sites. The Suffield sites are now included in the WAD project which will make recommendation for the clean-up of areas that have been determined to contain dangerous material.

The BCDRC notes that the Defence R&D Canada Human Performance Client Group 6 Service Level Agreement (CG 6 – SLA) 2005 – 2008, which defines the BCD program, has included the need to increase the capacity for Good Laboratory Practice (GLP) standards as discussed in previous BCDRC reports and recommended by the BCDRC in 2000.

Since 2000, the BCDRC has monitored the evolution of DRDC into a revenue generating entity with more independence from DND than it had previously enjoyed. After five years, it is becoming apparent that the relationship between DND and DRDC has changed. DRDC Suffield, the establishment of primary interest to the BCDRC, has been successful generating revenue through the use of its unique BCD training facilities and by obtaining funding for joint research projects with, among others, agencies of the United States government. However, DND provides an annual budget to DRDC for scientific and technological leadership and defence R&D. If DRDC is using its resources to generate revenue, can it be devoting as much effort as previously to the DND program? DRDC feels that it can if DND continues to fund improvements to infrastructure and DRDC's new revenue can be used to hire additional research and training staff. The balance between new staff and new or rebuilt laboratories for them to work in is an important issue. The BCDRC notes that DRDC identifies in the SLA the shortage of suitable laboratory space including Level III containment laboratories (see Annex C for information about Level III).

A critical resource at DRDC Suffield is Level III Containment. Level III laboratories are required for defensive research with biological agents. Suffield has two

Level III labs with a third small one coming on line which will be part of the CTTC (counterterrorism centre) facility. The two existing laboratories are fully utilized and DRDC Suffield has been unable to contract for time in equivalent Canadian facilities elsewhere. The prognosis for the next five to ten years for lab space is not good but the situation may become even worse in the future because it is predicted that the existing two laboratories can only be used for ten more years.

During three of its visits in 2005 the BCDRC received information about decontamination of personnel and equipment. At Land Force Western Area (LFWA) Headquarters, Edmonton, Alberta, the Committee received a briefing about the Decontamination Platoon in the General Service Battalion and then saw a demonstration of the platoon at work. The Committee was informed of a decontamination exercise which was held in Wainwright, Alberta. At the Joint NBCD Company, Trenton, Ontario the Committee heard that the Decontamination Platoon in the Company is comprised mainly of members of the military firefighter trade. The Company briefing included details about a decontamination exercise in CFB Petawawa. At Canadian Forces Support Training Group, Base Borden, Ontario the BCDRC heard about the amalgamation of the Nuclear Biological and Chemical School (CFNBCS) with the Firefighter Academy (CFFA). We heard that military firefighters are trained to fight fires in areas contaminated with dangerous substances (toxic industrial chemicals or TICs) and so are well trained for a decontamination role.

CONCLUSIONS

In the opinion of the BCDRC, samples of anthrax that were being transferred in a courier van that was involved in a collision in the city of Winnipeg posed no threat to the environment or to the Canadian public. The transporting of biological samples from the DRDC facility in Suffield is conducted safely. The Committee is satisfied that the anonymity provided by using private carriers provides a good degree of security and use of public vehicles and escorts would be costly and would draw unnecessary attention to the shipment.

The BCDRC is encouraged that DND is acting responsibly in its efforts to remediate contaminated sites and looks forward to further reports about the WAD project.

The shortage of Level III containment laboratories at Suffield may become critical if a plan to construct new facilities there is not put in action. The shortage of laboratory space at Suffield will have a serious negative effect upon the BCD program.

The BCDRC noted some differences in decontamination practices among the CF organizations. Some drills practiced in Western and Eastern Canada differ because of climate, geography and, perhaps, exercise scenarios. The Committee is of the opinion that decontamination is an important role but is concerned because the work is very labour intensive. With so many tasks for the military to complete, it must be difficult for the CF to justify employing soldiers in this role. The Committee is of the opinion that if

decontamination became a secondary responsibility of the firefighter trade, it might be easier to retain it among the tasks of the CF and the important lessons learned by the current organizations might not be lost.

RECOMMENDATIONS

The BCDRC will not make a second recommendation about the transfer and use of chemical and biological agents and toxins to civilian facilities. A 2002 recommendation remains in Annex B. The Committee will continue to monitor this activity.

In 2004, the committee made a recommendation about the balance of scientists, laboratories and equipment in the BCD program. In 2005, the attention of the BCDRC was drawn particularly to the limited number of available Level III containment facilities but feels that the need for these laboratories is covered by the 2004 recommendation.

The BCDRC encourages DND to retain and utilize the knowledge and expertise it has in the fields of equipment and manpower decontamination.

ANNEX A to BCDRC 2005 Annual Report

IMPLEMENTATION OF BARTON REPORT RECOMMENDATIONS

The current implementation status of the Barton Report recommendations was ascertained to be:

GENERAL

1. In the course of the annual program and budgetary process, the authorizing officer at each level be required to sign a certificate of compliance with Departmental policies.

Certificates of Compliance for 2005 were reviewed and found to be in order.

2. A senior Review Committee be established in association with the Defence Science Advisory Board (DSAB).

The BCDRC constitutes such a Committee. In 1997 the Committee was removed from the aegis of the DSAB and established as a selfadministering agency. In 2005, it became an organization reporting to the Canadian public rather than to the Chief of the Defence Staff and the Deputy Minister of National Defence.

3. "Second opinions" should be obtained from outside sources on some of the potentially controversial test programs.

The BCDRC suggested that the most effective way to obtain credible second opinions would be to establish external committees and to encourage collaboration through workshop type conferences. Defence Research and Development Branch (which became Defence R&D Canada in 2000) held a Technology Investment Workshop on biotechnology in November 1996. Also an independent Peer Review of the DRES (DRDC Suffield) BCD R&D program was conducted in June 1997. In 2000, DRDC established a permanent Advisory Board. It is co-chaired by the Chief of Defence Staff and the Deputy Minister of National Defence and has as members the Vice Chief and Deputy Chief of Defence Staff, the Chiefs of Air, Maritime and Land Staffs, and other individuals at the associate deputy minister level. The Director General Health Services is also a military member. Industry, academia and medicine are also represented. 4. A document be prepared annually which would set out the nature of the research and development work under way, the number of people involved, and allocated funding.

The 1990/91 Chief Research and Development (CRAD) Review was published in February 1992 and the 1991/92 Review in January 1994. The Defence Research and Development, Science and Technology for the New Century was published in March 1996. The initial Defence Research and Development Branch Outline of Program was published in April 1996, the second edition in June 1997 and the third edition in June 1998. The branch produced its first annual report, covering the fiscal year 1998/99. DRDC has continued this practice. These reports satisfy this recommendation. The 2004-2005 Annual Report is on the DRDC web site: http://www.drdc-rddc.gc.ca under "publications". The site includes a second informative document titled Looking Forward Staying Ahead ...Connecting With Users and Partners.

5. A layman's pamphlet be published which would help improve public understanding about Biological and Chemical Defence.

An appropriate departmental pamphlet was published in August 1990. A similar pamphlet entitled "Meeting the Challenge - Research and Development in Defence Sciences and Technologies", emphasizing the work at DRDC Suffield, was published in April 1993. The web site (http://www.drdc.dnd.ca or www.drdc-rddc.gc.ca) has been established and provides the public with information on biological and chemical defence work. The DRDC Suffield web site is also useful. Some of the CB Defence work is described at http://www.suffield.drdc-rddc.gc.ca/ResearchTech/Products/CB_PRODUCTS/index_e.html

6. **A DND directive on policies and procedures regarding the use of** volunteers and animals be published.

DND Policy - Animal Use in R&D was issued on 15 June 1989. Defence Administrative Orders and Directives (DAOD) 5061-0 and 5061-1, Research Involving Human Subjects, were issued on 20 August 1998. These administrative orders may be viewed on the DAOD web site at: <u>http://www.admfincs.forces.gc.ca</u>. Click on DAODs on the left side of the page.

DRES (DRDC Suffield)

1. A procedure be established to ensure that the DRES Safety Manual is reviewed at prescribed regular intervals of not more than three years. Safety drills should also be conducted at prescribed regular intervals.

An effective, dynamic safety program has been established. Drills and exercises are conducted and any safety related issues are resolved quickly.

2. An automatic annual review and certification procedure be instituted to confirm that stocks of toxic agents are being kept to the minimum level necessary for the conduct of an efficient research and development program.

The annual inventory audit was reviewed by the BCDRC in May 2005. Chemical and biological agent holdings were verified then. The committee agrees that stocks are being properly maintained at a minimum level, which in most cases is only a fraction of the authorized levels.

3. The arrangements being implemented to improve security and access controls be expedited.

With the possibility of terrorist attacks on critical infrastructure, security and access at DRDC Suffield are reviewed continuously.

4. Pending the destruction of the excess agent stocks now stored in the Experimental Proving Ground (EPG), the adequacy of existing physical security arrangements be reviewed with a view to strengthening them.

Completed.

5. The incinerator which is to be acquired for the program be considered for use in the destruction of other dangerous industrial chemicals, including PCBs.

The Alberta Provincial Government legislated this recommendation unimplementable. The incinerator was sold and its removal from DRES was completed by 6 August 1992.

6. The Experimental Proving Ground (EPG) operation and maintenance be given "project" status within the CRAD program.

Implemented. Thus positive visibility is given to all activities, funding and personnel involved in the EPG and ensures an annual review as a separate program component. 7. The scope of the safety and environmental requirements governing outdoor testing at DRES be determined by the provisions of the Canadian Environmental Protection Act.

Although the present Act does not include such express provisions, the Federal Minister of Environment has said that the department will develop the requisite guidelines as and when necessary. In addition, a staff control system is in place and functioning to ensure compliance with all constraints.

8. A full environmental audit of DRES be commissioned as soon as possible and that it be repeated at regular intervals of, say, five years.

Acres Consultants Ltd, having completed the audit under a Supply and Services Canada contract, submitted their final report in February 1992. An internal staff agency was created to initiate recommendation compliance. All the Report's recommendations have been addressed and full compliance is anticipated. The Acres' report has been deposited with the Canada Institute for Scientific and Technical Information (CISTI), the National Library and major university libraries throughout the country. The first follow-on audit was conducted by Acres International Ltd in early 1997 and the report was received at DRES on 31 March 1997. A second five year audit was not conducted by May 2002. However, the Auditor General has conducted an Environmental Audit and Suffield has implemented an Environmental Management System. Also, significant progress has been made on recommendations in the previous independent audit. A full assessment of DND hazardous sites is underway, including those at Suffield. The study that is underway is developing a methodology for cleaning up the various sites. At Suffield, there is a potential hazard from old munitions containing mustard and nerve gas. Cleaning the subsoil and handling material buried in it will be challenges at Suffield.

DREO (DRDC Ottawa)

The entire Defence Research Establishment Ottawa (DREO) chemical agent inventory has been destroyed, all storage and handling facilities removed, laboratories dismantled and the facility decommissioned. The BCDRC ceased reporting on DREO (DRDC Ottawa) activities in 1994.

ANNEX B to BCDRC 2005 Annual Report

IMPLEMENTATION OF BCDRC REPORT RECOMMENDATIONS

<u>Note</u>: Once a recommendation has been complied with to the satisfaction of the Committee it will cease to be included in subsequent Reports. However, if the effect of the recommendation is of a continuing nature it will be subject to periodic monitoring by the Committee.

1. The flow of information within the Defence Research laboratories between sections, management and staff might be improved -possibly through occasional informal meetings and discussions with senior managers. (1990)

There is always room for improvement in communications. The staff at DRDC Suffield is growing. New people must be kept informed. Monitoring of the flow of information at DRDC Suffield and DRDC Headquarters will continue.

2. The Annual Agent Inventories Audit Reports be restructured as follows:

- a. biological agents used for research purposes are to be identified by complete strain or antigenic designator;
- b. stocks of biological agents are to be quantified in meaningful terms; i.e., infectious titres or colony-forming units per given volume;
- c. stocks of biological agents that are clearly not agents of biological warfare should be identified as such with an accompanying statement to the effect that such agents may be found in Public Health, University and Industrial laboratories. (1993)

Approved. This work will be completed in accordance with a schedule agreed to by BCDRC and DRDC Suffield. There is satisfying progress and monitoring will continue. This recommendation will be assessed in 2006 with the intention of removing it from this list of recommendations if progress has been satisfactory.

3. The BCDRC be contractually guaranteed access to all private sector laboratories that become involved in the Biological and/or Chemical Defence Research and Development program either under the prevailing contracting system or through the auspices of the industrial partnership proposal. (1994)

This recommendation was approved in 1994. Although contractors routinely provide formal briefings to BCDRC during our annual visits to DRDC Suffield and DRDC Toronto and circumstances have yet to arise when BCDRC has considered an on-site visit necessary, the committee does not have guaranteed access to such private sector laboratories. The position of the BCDRC outlined in the 2001 report was that a standard clause should be included when other public sector or private sector laboratories are contracted to carry out BCD-related work for DND. ADM (S&T) and the Chair of the BCDRC have agreed on the wording of this clause and BCDRC awaits its incorporation into contracts between DRDC and private sector laboratories. The BCDRC will schedule a visit to a private sector laboratory in the future.

4. The CFNBC School Training Library collection be reviewed and dated reference material be replaced. Additionally, the ability to access information servers, e.g.; Internet or World Wide Web, be provided. (1995)

Agreed. Marked progress has been made in this endeavour. The library has Internet access and is using it to obtain increased amounts of scientific material. Since 2001, the library has been able to purchase several new and useful reference text books. Monitoring will continue.

5. The skills of the present DRDC Suffield Staff be reviewed to ensure that no critical imbalances have been created that might affect productivity, safety or responsiveness. (1996)

The DRDC Suffield staff is under continual review. Safety remains a concern as the size of the staff increases. The chairman of the Safety committee keeps the issue in the forefront. A hiring freeze in the 1990s produced a gap in the age range of defence scientists. This has meant that much younger scientists are moving into management as older scientists retire. This in turn has reduced the ranks of younger scientists conducting research. On the positive side, recruitment of new scientists to work in the CTTC and on CRTI projects has begun. DRDC Suffield reported in May 2005 that staffing of two biologists has been completed and work to hire three chemists would be starting soon. The Committee will continue to monitor the staffing issue. BCDRC reminds DRDC that DRDC Suffield has agreed to keep the Committee informed of staff changes.

6. The DRDC Suffield Safety Manual and Emergency Response Plans be up-dated and tested at least annually. (1996)

Agreed. Monitoring will continue. The DRDC Suffield General Safety Officer conducts a dynamic program. He has added computer-based training and uses the DRDC Suffield local area network to circulate safety information. He is conscious of the need to ensure that new staff is trained in safety procedures and he has brought the issue to the attention of management.

7. The BCDRC mandate be amended to include an annual visit to Health Canada's Canadian Science Centre for Human and Animal Health in Winnipeg whenever research is being conducted there either by or directly for DRDC Suffield. (1999)

Health Canada and DND have signed a memorandum of understanding for collaborative work. The Winnipeg laboratory is involved in some CRTI projects and the BCDRC visited the centre in 2004. Annual visits are not required. This recommendation will be removed after a second visit.

8. To facilitate the Health Canada approval process for new medical countermeasures against chemical and biological agents, it is recommended that eventual regulatory requirements be considered at early stages of R& D and all data be collected and records maintained according to Good Laboratory Practice (GLP) guidelines. (2000)

Approved. The recommendation is being implemented on a case by case basis. The need for GLP remains important to the regulatory process and more attention should be paid to its implementation. In 2005, DRDC Suffield reported that laboratories were being reconfigured to be suitable for GLP work. Training would be conducted for DRDC Suffield staff so they will be able to conduct research according to the GLP guidelines. The required GLP record system will be implemented. Staffing of new positions required to implement the GLP is in progress. DRDC Corporate Headquarters provided additional information about the HI-6 Nerve Agent Antidote Project at Suffield which will become GLP compliant.

9. It is recommended that DRDC establish a mechanism to ensure that Human Research Ethics protocols from defence research establishment scientists are evaluated consistently, expeditiously and according to the latest TriCouncil Policy Statements on Ethical Conduct for Research Involving Humans. (2001) Note: the TriCouncils are the Natural Sciences and Engineering Research Council of Canada; the Social Sciences and Humanities Research Council of Canada and the Canadian Institutes of Health Research.

The recommendation is accepted. DRDC is establishing policy to ensure that any updates in TriCouncil Guidelines concerning research involving human subjects are incorporated into the review process. A single DRDC Human Research Ethics Committee exists at DRDC Toronto where much of the human research is conducted. This recommendation may be removed if the BCDRC is satisfied with progress during its next visit to DRDC Toronto.

10. It is recommended that an arms-length committee of civilian professionals be formed to serve an advisory role to CFMG on biological and chemical medical countermeasures or that the mandate of the BCDRC be changed to include this responsibility. (2001)

The recommendation has been agreed to and CFMG intends to establish such a committee. The recommendation will be discussed during 2006 visits.

11. It is recommended that the BCDRC be informed when containers or expended rounds that may contain live agent are discovered at any facility. (2001)

The recommendation has been accepted. The responsibility for reporting contaminated containers or rounds to the BCDRC has been shifted from DRDC Suffield to DAPC Policy at NDHQ. This may seem a circuitous route for reporting. However, DAPC Pol has national responsibility for reporting such discoveries to the Organization for the Prohibition of Chemical Weapons (OPCW) which oversees the implementation of the Chemical Weapons Convention (CWC). Reporting to the Committee by DAPC Pol has been reliable.

12. It is recommended that doctrine be developed for the provision of medical care in biological and chemical warfare (BCW) conditions. (2002)

Accepted. A staff officer has been appointed and doctrine will be formalized. Canada is involved with other nations in the development of doctrine. 13. It is recommended that Defence R&D Canada (DRDC) prepare guidelines for the transfer and use of chemical and biological agents and toxins to civilian facilities taking into account the concerns of the BCDRC as already expressed both in this report and separately to DRDC. (2002)

Accepted. DRDC Headquarters (Director Science and Technology Human Performance) has prepared the guidelines and current DND regulations are being enforced. The BCDRC is attempting to monitor the transfer of agents. The BCDRC was promptly informed about the vehicle collision in Winnipeg which involved the transfer of biological material. The incident is discussed in the body of the 2005 report.

14. The BCDRC recommends that the process of obtaining Health Canada approval for medical countermeasures be given more attention by DND. The BCDRC would like to see policy drafted by an interdepartmental committee (HC and DND) which addresses the extraordinary use of MCM that are approved for use within the military. (2003)

Accepted. The full approval of medical products is difficult because of the HC requirement for human efficacy trials. DND cannot test on humans the efficacy of (for example) a medical countermeasure for nerve agent poisoning. The department must depend on "special access" approval for a restricted population such as CF members. DND has been proposing an interdepartmental committee consisting of representatives from the CF. Health Canada Therapeutic Products Directorate (TPD) and Public Safety and Emergency Preparedness Canada (PSEPC) but has not had a response from Health Canada. Some progress is being made. One new drug submission that was filed with Health Canada in August 2001 has been placed on Regulatory Hold, stating that the submission is not approvable until an amendment to the Food and Drug Act and Regulations is implemented to permit regulatory approval based on appropriate animal efficacy data. This possibility that animal efficacy data will be acceptable rather than human efficacy data is encouraging. However, the amendment to the act must be passed for the change to be implemented. A Health Canada Memorandum to Cabinet addressing this issue was in preparation this year. DND has also submitted a Memorandum to Cabinet on the subject.

15. The BCDRC recommends that research in BCD be given the utmost priority in DRDC Suffield. Rather than employing researchers to supervise training, other arrangements should be found. Therefore, the BCDRC encourages the completion and manning of the CTTC if that will permit scientists to conduct more research. (2003)

The Committee continued to see improvement in 2005. The CTTC is reducing the load placed by training on the R&D program. Five new positions in the CTTC may relieve R&D program personnel from all training commitments in 2005. Facilities for the CTTC will free space for the research scientists and their staff.

16. The BCDRC recommends that the biological and chemical defence program in the Department of National Defence continue with undiminished resources. (2004)

No response to this recommendation has been received.

17. The BCDRC recommends that a suitable balance be kept among increases in the number of researchers and increases in laboratory space and equipment within the BCD program during the current period of growth to meet research commitments. (2004)

This issue was discussed at length during the 2005 visits. The problem is complex and involves how DRDC is funded by DND and for what. Work to maintain a balance will be a major effort during the next few years.

18. The BCDRC recommends that some attention be paid to shortcomings in the working relationships of the Joint NBC Defence Company. (2004)

The Joint NBC Defence Company is becoming more established. Some shortcomings remain in working relationships and the Committee will continue to monitor them.

ABBREVIATIONS AND TERMS

ADM: Assistant Deputy Minister; Associate Deputy Minister

ADM (S&T): Assistant Deputy Minister Science and Technology

BCDRC: Biological and Chemical Defence Review Committee

BCD: Biological and Chemical Defence

BCW: Biological and Chemical Warfare

BTWC: Biological and Toxins Weapons Convention

CBRN: Chemical, Biological, Radiation and Nuclear

CDS: Chief of the Defence Staff

CISTI: Canadian Institute for Scientific and Technical Information

CF: Canadian Forces

CFNBCS: Canadian Forces Nuclear, Chemical and Biological School

CFMG: Canadian Forces Medical Group

CFMG Op Med: CFMG Operational Medicine: the group in CFMG that supervises the development of MCM

CG: Client Group

CMBG: Canadian Mechanized Brigade Group

CMED: Central Medical Equipment Depot

CRAD: Chief of Research and Development; from 2000, the Assistant Deputy Minister Science and Technology

CRTI: Chemical, Biological, Radiological/Nuclear Research and Technology Initiative (for details, please refer to the web site: <u>http://www.crti.drdc-rddc.gc.ca/</u>.)

CT: Counter-terrorism

CTTC: Counter Terrorism Technology Centre

CWC: Chemical Weapons Convention

DAOD: Defence Administrative Orders and Directives (see the web site at <u>http://www.admfincs.forces.gc.ca</u>)

DAPC Pol: Director of Arms Proliferation Control Policy. The abbreviation also refers to the directorate.

DCDS: Deputy Chief of the Defence Staff

DCIEM: Defence and Civil Institute of Environmental Medicine; in 2002 became DRDC Toronto (see DRDC)

DFAIT: Department of Foreign Affairs and International Trade (see FAC)

DGHS: Director General Health Services

DM: Deputy Minister

DNBCD: Director of Nuclear, Biological and Chemical Defence. The abbreviation also refers to the Directorate.

DND: Department of National Defence

DRDB: Defence Research and Development Branch; in 2000 became DRDC

DRDC: Defence R&D Canada is the preferred title (see the web site at http://www.drdc.dnd.ca)

DRE: Defence Research Establishment

DREO: Defence Research Establishment Ottawa; in 2002 became DRDC Ottawa

DRES: Defence Research Establishment Suffield; in 2002 became DRDC Suffield

DSAB: Defence Science Advisory Board

EPG: Experimental Proving Ground

FAC: Foreign Affairs Canada (replaces DFAIT)

GLP: Good Laboratory Practice

JNBCD Coy: Joint Nuclear Biological and Chemical Defence Company (the company will have 93 members when it is complete)

HC: Health Canada

HREC: Human Research Ethics Committee

LCDC: Laboratory Centre for Disease Control; renamed the Canadian Science Centre for Human and Animal Health

Level III Containment or Level III:_A high level of physical containment requiring a dedicated laboratory with independent air supply and security features. For more information please see <u>http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-</u>96/lbg5_e.html#5.3

LFWA: Land Force Western Area

MARLANT: Maritime Forces Atlantic

MCM: Medical Countermeasures

MOU: Memorandum of Understanding

NATO: North Atlantic Treaty Organization

NDHQ: National Defence Headquarters

NBC: Nuclear, Biological and Chemical

NBCRT: Nuclear, Biological and Chemical Response Team

NML: National Microbiology Laboratories (located at the Canadian Science Centre for Human and Animal Health in Winnipeg)

OCIPEP: Office of Critical Infrastructure Protection and Emergency Preparedness (see PSEPC)

OPCW: Organization for the Prohibition of Chemical Weapons

PCB: polychlorinated biphenyls

PSEPC: Public Safety and Emergency Preparedness Canada. Replaced OCIPEP in 2003.

PWGSC: Publics Works and Government Services Canada

UNSCOM: United Nations Special Commission on Iraq

R&D: Research and Development

RSDL: reactive skin decontamination lotion

SLA: Service Level Agreement. The Defence R&D Canada Human Performance Client Group 6 Service Level Agreement (CG 6 – SLA) 2005 – 2008 defines the BCD programme in Thrust 16q.

SWE: Salary and Wage Envelope

TICs: Toxic Industrial Chemicals

TPD: Health Canada Therapeutic Products Directorate

VCDS: Vice Chief of the Defence Staff