



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

Record of Proceedings, Including Reasons for Decision

In the Matter of

Licensee
Subject to
Order

Health Canada

Subject

Opportunity to be Heard on the Designated
Officer Order Issued to Health Canada National
Dosimetry Services on February 23, 2012 and
Dosimetry Service Licence Amendment Request

Date of
Opportunity to
be Heard

March 29, 2012

RECORD OF PROCEEDINGS

Licensee/Person named in
or subject to order: Health Canada

Address/Location: 269 Laurier Avenue, Ottawa, Ontario, K1A 0K9

Purpose: Opportunity to be heard on the Designated Officer Order issued to
Health Canada National Dosimetry Service on February 23, 2012
and Dosimetry Service Licence Amendment Request

Order Issued: February 23, 2012

Date of Opportunity
to be Heard: March 29, 2012

Location: Canadian Nuclear Safety Commission (CNSC) Public Hearing
Room, 280 Slater St., 14th. Floor, Ottawa, Ontario

Members present: M. Binder, Chair

Secretary: M.A. Leblanc
Recording Secretary: D. Carrière

Order: Confirmed
Licence: Amended

Table of Contents

Introduction	- 1 -
Decision	- 2 -
Issues and Commission Findings	- 2 -
<i>Actions and Measures of the Order</i>	- 4 -
<i>Application of the Licensee to revoke the Order</i>	- 4 -
<i>Licensee's response to Order 0685</i>	- 5 -
<i>Licence Amendment Request</i>	- 5 -
<i>Application of the Canadian Environmental Assessment Act</i>	- 6 -
Conclusion	- 6 -

Introduction

1. On February 23, 2012, a Canadian Nuclear Safety Commission¹ (CNSC) Designated Officer issued an Order to Health Canada for its National Dosimetry Services (NDS) as a result of a second unplanned event (both events involve the reporting by the NDS of erroneous radiation doses to extremities). The Order required NDS to immediately comply with specific actions and measures identified in the Order. Among other actions and measures, the Order required that the NDS immediately cease reporting extremity doses, provide evidence that appropriate processes had been put in place to ensure that no further inadvertent extremity dose reporting would occur, and await CNSC authorization to restart the service.
2. Pursuant to subsection 37(6) of the *Nuclear Safety and Control Act*² (NSCA), the Designated Officer referred the Order to the Commission for review.
3. Pursuant to paragraph 40(1)(d) of the NSCA, the Commission provided an opportunity to be heard to Health Canada, as the licensee subject to and named in the Order.
4. In a separate request submitted to the CNSC on December 21, 2011, the NDS applied for an amendment to its dosimetry service licence to reflect the newly developed and implemented procedures for verification of the performance of the extremity dosimetry system and further requested on March 16, 2012, to reference the corrective action plan. Licence amendment requests for dosimetry service licences are normally considered by the Designated Officer. However, this licence amendment request was delayed as a consequence of Order 0685, requiring NDS to await authorization from the Commission to reinstate reporting of extremity doses. This licence amendment request is being considered concurrently with the Commission review of the Designated Officer Order to facilitate the timely resumption of reporting of the dosimetry results required by NDS clients.

Issue

5. In its review of the Order, the Commission was required to confirm, amend, revoke or replace the Order, pursuant to subsection 37(6) of the NSCA.
6. In considering the licence amendment application, the Commission was required to decide, pursuant to subsection 24(4) of the NSCA:
 - a) if Health Canada is qualified to carry on the activity that the amended licence would authorize; and
 - b) if in carrying on that activity, Health Canada would make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

¹ The *Canadian Nuclear Safety Commission* is referred to as the “CNSC” when referring to the organization and its staff in general, and as the “Commission” when referring to the tribunal component.

² Statutes of Canada (S.C.) 1997, chapter (c.) 9.

Hearing

7. Pursuant to section 22 of the NSCA, the President of the Commission established a Panel of the Commission to review the Order and the licence amendment application. The Commission, in making its decision, considered information presented for a hearing held on March 29, 2012 in Ottawa, Ontario. The proceeding was conducted in accordance with the *Canadian Nuclear Safety Commission Rules of Procedure*³. The Commission considered the Designated Officer Order 0685, including information referred to in the Order, and considered written submissions from CNSC staff (CMD 12-H115) and Health Canada (CMD 12-H115.1).

Decision

8. Based on its consideration of the matter, as described in more detail in the following sections of this *Record of Proceedings*,

the Commission, pursuant to subsection 37(6) of the NSCA, confirms the Designated Officer Order issued to Health Canada on February 23, 2012 and is satisfied that Health Canada has complied with the terms of the Order. The Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, amends the Dosimetry Service Licence 20052-36-16.0 issued to Health Canada for its National Dosimetry Services located in Ottawa, Ontario. The amended licence, 20052-36-16.1, remains valid until May 31, 2016.

Issues and Commission Findings

9. In reviewing the Order under subsection 37(6) of the NSCA, the Commission considered the reasonableness of the Order. In this regard, the Commission considered the actions and measures identified in the Order and the information on which the Order was based, as identified in the Order. As elaborated below, the Commission is satisfied that the Designated Officer, based on the information available, had sufficient evidence and a reasonable basis for issuing the Order.

Background

10. Health Canada currently holds CNSC Dosimetry Service Licence No. 20052-36-16.0 that authorizes the licensee to operate the National Dosimetry Services (NDS) in compliance with the NSCA and its Regulations, the licence conditions, and the standards and documents referenced in the licence to ensure that doses measured are accurate, precise and reliable.

³ Statutory Orders and Regulations (S.O.R.)/2000-211

11. On October 18, 2011, NDS reported an unplanned event to the CNSC after discovering that the dose algorithm used to calculate the extremity doses for wrist and ring dosimeters was not the same as the one that was authorized by the CNSC dosimetry service licence. This error resulted in wrist doses being under reported by 25% and ring doses being under reported by 40% since July 2008.
12. Immediately after the unplanned event was reported to CNSC staff, the Designated Officer for dosimetry services issued a request pursuant to subsection 12(2) of the *General Nuclear Safety and Control Regulations*⁴, asking NDS to notify all clients of the error, file a report describing the validation performed by NDS to ensure the appropriateness of the changes made to correct the algorithm, and file a detailed report on the event. NDS presented their response to the 12(2) request at a Public Commission Meeting held on December 15, 2011. During this Meeting, it was reported that three doses were found just above the dose limits, but well below the thresholds where health effects are likely to occur.
13. In its response to the unplanned event and to the 12(2) request, NDS committed to suspend all reporting of extremity dosimetry results until a third party validation of appropriate implementation of the changes to NDS' dose management system was performed, and until changes to the procedure documents detailing the verification process for performance of extremity dosimeter assignments were completed.
14. On February 10, 2012, NDS advised the CNSC that extremity dose reports had been inadvertently sent to clients on January 12, 2012. A detailed report of this unplanned event was submitted to the CNSC on February 17, 2012, which showed that 128 clients (representing 747 individuals) using the extremity dosimetry service received uncorrected extremity dose reports after NDS had agreed to suspend reporting. CNSC staff stated that this error indicates that the measures put in place by NDS to suspend reporting to correct the calculation errors and to improve the quality assurance program had failed.
15. On February 23, 2012, the Designated Officer responsible for dosimetry licensing issued Order 0685 to NDS pursuant to paragraph 37(2)(f) of the *Nuclear Safety and Control Act* (NSCA), to require that NDS immediately cease reporting extremity doses, provide evidence that appropriate processes had been put in place to ensure that no further inadvertent extremity dose reporting would occur, and await CNSC authorization to restart the service.

⁴ S.O.R./2000-202

Actions and Measures of the Order

16. NDS was ordered to undertake several actions and measures. NDS was required to:
- Immediately cease all reporting of extremity dosimetry doses to both the clients of NDS and the National Dose Registry (NDR);
 - Provide, within seven days, evidence of the implementation of the four corrective actions identified in the February 17, 2012 “Detailed Report of an Unplanned Event” submitted by NDS by:
 - informing NDS staff of the event, and reminding staff of the importance of ensuring that procedures are followed and that work is performed properly and verified;
 - preventing extremity reports from being accidentally printed/reported, and implementing a software control;
 - producing, as a secondary check, a Summary Report following the generation of future exposure reports that shall be reviewed by the Technical Supervisor to ensure that no wrist or ring extremity reports were generated before the permission for reports to be mailed be granted;
 - clients were informed on February 17, 2012 that they had inadvertently received extremities exposure reports, and that these reports will be replaced by new exposure reports once NDS formally resumes reporting of data to NDR and to clients; and
 - instructing clients to destroy the current reports, and that no further action is required from clients as data was not sent to the NDR.
 - Complete NDS change control process as soon as possible and within 30 days, and provide evidence of the suspension of extremity dose reporting;
 - Demonstrate, within 30 days, that NDS change control process for the change to the dose algorithms has been completed, and confirm that the change control process has been reviewed by a qualified independent 3rd party; and
 - Await authorization from the CNSC Designated Officer to recommence reporting extremity dosimetry doses to both NDS clients and to the NDR.

Application of the Licensee to revoke the Order

17. On March 12, 2012, Health Canada filed their request for an opportunity to be heard regarding Order 0685, which summarized NDS response to the unplanned event, compliance with the 12(2) request, the implementation of a corrective action plan, and the response to the inadvertent release of dosimetry results. Health Canada also requested the revocation of the order.
18. NDS requested that the Order be revoked on the basis of two interpretations. The first being that the inadvertent release of dosimetry results did not impact the health and safety of workers, or the accuracy, reliability or precision of the dosimetry results as the data was not reported to the NDR. CNSC staff reported that they do not concur with NDS’ interpretation, stating that the provision for incorrect dose reports to clients

is important evidence that dosimetry results were inaccurate and unreliable. CNSC staff further reported that NDS' clients are licensees who are authorized to perform activities under the NSCA and who make decisions regarding the radiation protection requirements for their workers, and that the health and safety of workers may be directly influenced by receiving under reported dosimetry results.

19. In its second interpretation, NDS stated that it does not consider this event to be an unplanned event as defined in its licence conditions, but rather a non-conformance requiring corrective measures but not warranting regulatory action. CNSC staff reported that they do not concur with the NDS' interpretation, explaining that while non-compliance requiring corrective actions and unplanned events are not clearly differentiated, the threshold for differentiating the two is normally whether the Quality Assurance Program of a dosimetry service identifies the problem before doses are reported to the workers or to the NDR. CNSC staff stated that, in this case, the processes that NDS had in place failed to stop inaccurate dose information from reaching their clients and that NDS was notified of this error through a client.
20. As a result, CNSC staff recommends that the Designated Officer Order 0685 be confirmed by the Commission.

Licensee's response to Order 0685

21. On February 29, 2012, NDS responded to Order 0685 to demonstrate compliance with each of the requirements of the order. CNSC staff reported having reviewed the documentation submitted by NDS and found that NDS has demonstrated compliance with each of the requirements of the order, as further detailed in CMD 12-H115 and CMD 12-H115.1.

Licence Amendment Request

22. On December 21, 2011, NDS submitted a request to amend the dosimetry service licence. NDS later re-confirmed this request on March 16, 2012 following review of the documents in support of the application, including the corrective action plan. NDS is requesting changes to documents referenced in the Appendix: *Licence Documents* in the licence to reflect the newly developed and implemented procedures for verification of the performance of the extremity dosimetry system and to reference the corrective action plan. An amendment of the licence to reflect these updated procedures would allow NDS to resume reporting extremity doses to their clients.
23. CNSC staff reported having reviewed NDS' licence amendment request and the supporting documentation against the criteria specified in the standard "*S-106 Revision 1, Technical and Quality Assurance Requirements for Dosimetry Service*". CNSC staff stated that they consider that the procedures documented in these documents meet the requirements of the applicable sections of *S-106 Revision 1*. CNSC staff summarized the changes made to the documents to meet the requirements of *S-106 Revision 1* in CMD 12-H115.

24. CNSC staff also reported having reviewed the corrective action plan proposed by NDS. CNSC staff found that the corrective action plan adequately addresses the root causes identified in the root cause analysis performed by NDS after the events. CNSC staff recommended that the Commission amend the licence, as per Health Canada's application.

Application of the Canadian Environmental Assessment Act

25. Before making a licensing decision, the Commission must be satisfied that all applicable requirements of the *Canadian Environmental Assessment Act*⁵ (CEAA) have been fulfilled.
26. CNSC staff reported that it had completed an Environmental Assessment (EA) determination. CNSC staff stated that there was no requirement for an EA pursuant to subsection 5(1) of the CEAA for the proposed licence amendment.

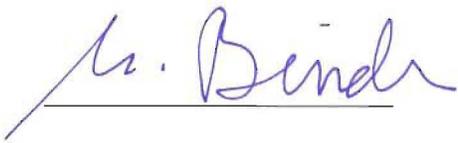
Conclusion

27. The Commission has considered the information and submission of Health Canada and CNSC staff as presented in the material available for reference on the record for the proceeding.
28. Based on the above information, the Commission, pursuant to paragraph 40(1)(d) of the *Nuclear Safety and Control Act*, confirms the Order issued by the Designated Officer to Health Canada on February 23, 2012 in the manner described in this *Record of Proceedings*.
29. The Commission is satisfied that Health Canada has complied with all of the requirements of the Order.
30. The Commission is also satisfied that Health Canada has proposed and taken corrective actions and has submitted revised operating procedures that demonstrate compliance with the requirements of the request pursuant to subsection 12(2) of the *General Nuclear Safety and Control Regulations*, Designated Officer Order 0685 and Regulatory Standard S-106 Revision 1, *Technical and Quality Assurance Requirements for Dosimetry Services*.
31. The Commission is satisfied that NDS meets the requirements of subsection 24(4) of the *Nuclear Safety and Control Act*. That is, the Commission is of the opinion that NDS is qualified to carry on the activity that the amended licence will authorize and that NDS will make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures

⁵ S.C. 1992, c. 37.

required to implement international obligations to which Canada has agreed.

32. Thus, the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, amends the Dosimetry Service Licence 20052-36-16.0 issued to Health Canada for its National Dosimetry Services located in Ottawa, Ontario. The amended licence, 20052-36-16.1, remains valid until May 31, 2016.
33. The Commission is satisfied that all applicable requirements of the CEAA have been fulfilled.



MAR 29 2012

Michael Binder
President,
Canadian Nuclear Safety Commission

Date