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| Procedure Title: WCF RSO Reporting to the Applicant Authority | | |
| Procedure Number: A022 | Revision: 2 | Date Prepared: July 8, 2022 |
| Prepared by: K. Franz | | Date Approved August 9, 2022 |
| Reviewed by: T. Biru | | Date Effective August 14, 2022 |
| Approved by: N. Schepp | | Page: i |

Revision History

| Revision | Effective Date | Notes |
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| 0 | May 1, 2016 | Prepared by K. Franz. Reviewed by Dr. A. Goertzen. Approved by Dr. S. Mzengeza. i. Initial version created as a requirement to satisfy new CNSC requirement. |
| 1 | August 1, 2021 | Prepared by K. Franz, Reviewed by T. Biru. Approved by Dr. A. Goertzen. Revised under change case CN.2021.006. i. Moved report from appendix of SOP to standalone form F20-210-01. ii. Added additional performance indicators to report. iii. Added executive summary for email. iv. Revised title to “WCF RSO Reporting to the Applicant Authority” from “WCF RSO Report to the Applicant Authority.” |
| 2 | August 14, 2022 | Prepared by K. Franz, Reviewed by T. Biru. Approved by N. Schepp. i. Revised under CN.2022.024. ii. Deleted SOP R404 in favor of this SOP as they shared the same information. iii. Added SOP review section and signature section on form. |

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1. PURPOSE AND BACKGROUND

Licencees must appoint an AA with sufficient authority/ability to ensure that there is access to funding for appropriate levels of staffing and/or equipment needed to safely operate and comply with the acts and regulations set forth by the CNSC. The AA for the WCF licences will be from a level of management that is capable of meeting these requirements. This generally means that the AA is not on site or involved with the day to day operations at the WCF. Therefore, this SOP will identify important KPIs and other general information at the WCF that will help to keep the AA informed and engaged in the status of the various licenced activities being performed at the WCF.

These KPIs are also valuable in providing the WCF staff of all the licenced activities occurring in the WCF. Therefore, this information will also be shared with the WCF staff to keep them engaged in the various RS items happening in their workplace.

2. DEFINITIONS

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| AA | Applicant Authority |
| ACR | Annual Compliance Report |
| CNSC | Canadian Nuclear Safety Commission |
| CRSC | Corporate Radiation Safety Coordinator |
| HSC | Health Sciences Centre |
| KPI | Key Performance Indicator |
| RS(O) | Radiation Safety (Officer) |
| SOP | Standard Operating Procedure |
| WCF | Winnipeg Cyclotron Facility |

3. SCOPE

This SOP is to be used by the WCF RSO as a guide to identify and prepare a report that will provide the AA with enough information about the staffing and resources available at the WCF that the AA is able to decide if the facility is operating safely. Further, this information will be provided to the WCF staff to ensure that they are engaged in the activities happening in their facility.

4. RESPONSIBLE

4.1. WCF RSO: Preparation of reports to the AA, the ACR and any additional RS reports as required.

5. SCHEDULE

- 5.1. Quarterly – Prepare and Share Reports with the AA, the WCF staff and Director.
- 5.2. Annually – ACR (may be provided in conjunction with the quarterly report).
- 5.3. As Required – Any additional information requested.

6. REFERENCE SOPS

- 6.1. SOP A020: Public Information and Disclosure Program.
- 6.2. Form & Instructions for F20-210-01: WCF RSO Quarterly Report to the Applicant Authority.

7. EQUIPMENT AND MATERIALS

- 7.1. Form F20-210-01: WCF RSO Quarterly Report to the Applicant Authority.
- 7.2. ACR as submitted to CNSC.

8. PROCEDURE

- 8.1. KPIs that the WCF report to the AA and WCF staff may include but are not limited to:
 - 8.1.1. Staff Exposure Reports – This section will provide a monthly max extremity and quarterly max whole-body dose report and will accrue the data over the entire year of reports. This information offers some insight into the effectiveness of the RS program and the safety of the workers.
 - 8.1.2. Reportable Incidents or Public Disclosures – This section will provide a monthly summary of any reportable incidents that may have occurred in the facility. When an incident leads to a public disclosure the date and a brief summary of the public disclosure will be provided to the AA. The AA is also on the list of recipients for public disclosure as described in SOP A020.
 - 8.1.3. WCF Licence Renewal, Amendments or Notable Items – This section is intended to provide a description of the change(s) made to the licence and provides information of an impending expiry and actions taken. This

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will keep the AA and WCF staff informed of the ongoing changes and improvements to the licence and the RS program.

- 8.1.4. Cyclotron Operational Status & Downtime – This section will provide information as it pertains to cyclotron performance, recent PMs or repairs and possible challenges/solutions encountered.
- 8.1.5. Radiopharmaceutical Production Status & Downtime – This section summarizes the production numbers for each month. Although FDG is the main product there is also a line for other radiopharmaceuticals.
- 8.1.6. WCF Inspections – This section will summarize any inspections that the WCF participated in along with any items that were found to be non-compliant.
- 8.1.7. WCF Staffing – This section will provide the AA with any relevant information regarding possible staff changes, additions or requirements in the WCF.
- 8.1.8. Research Updates – This section will discuss any recent additions, changes or advancements in the research program at the WCF.
- 8.1.9. Revised WCF RS SOPs and SH RSPs – Although this section is more for WCF staff, it does act to show how there are ongoing efforts to improving and maintaining a functional RS program.
- 8.2. The RSO will complete form F20-210-01 which will summarize all of the activities at the WCF for the quarter preceding the report.
 - 8.2.1. New year reports begin in May as this usually provides enough time for other required information to be available (i.e. 1st quarter dose reports).
- 8.3. Once the form has been completed, print the file as a PDF, this will save the contents of the completed form in a format that cannot be edited.
- 8.4. Attach the PDF to an email addressed to:
 - 8.4.1. The AA, The AA executive assistant (as required), The WCF director, the CRSC
 - 8.4.2. Provide an executive summary highlighting the contents and take away of the report.
- 8.5. Send the report, as prepared for the AA, to all WCF staff.
 - 8.5.1. The Director will sign the printed copy of the form after it has been reviewed (this may be done as part of the RSO & Director meeting or during a staff meeting where the report has been discussed).

9. ACCEPTANCE CRITERIA

- 9.1. Reports are to be provided to the AA quarterly.
- 9.2. ACRs will be provided to the AA annually when requested.