



Standards Council of Canada
Conseil canadien des normes



Fee Schedule for the Good Laboratory Practice Program Specialty Area

June 2002

STANDARDS COUNCIL OF CANADA

FEE SCHEDULE FOR THE GOOD LABORATORY PRACTICE PROGRAM SPECIALTY AREA

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This revised fee schedule for the SCC GLPMA program is based on a review of costs associated with the GLP activities of the GLPMA during the initial two-year cycle since inception of the SCC GLP PSA. It is also revised to more closely align with the revised PALCAN fee schedule for accredited laboratories. The revised fees are outlined with an explanation of activity and associated amount. The schedule details typical annual fees for both field sites and test facilities, plus fees for other GLP services, and details the policy regarding any refunding of fees paid to the GLP monitoring authority.

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A. INTRODUCTION

The SCC GLP program was established as, and remains, a Program Specialty Area (PSA) within the Program for the Accreditation of Laboratories-Canada (PALCAN). The initial SCC GLP fee schedule was established with the intention of reviewing after the initial start-up phase was completed to ensure that the fees continue to accurately reflect the costs experienced by SCC, and to ensure applicability and fairness to clients. The PALCAN fee schedule for accredited laboratories was recently revised and implemented. This revised fee schedule for GLP facilities within the GLP PSA more closely aligns with the structure and invoicing procedures of the PALCAN fee schedule.

This revised GLP fee schedule is also aimed at making it easier for clients to budget for participation in the program. The following are the key considerations in the redesign of GLP PSA fees:

- a) clear and discernible differences between client types and SCC GLP activities which can be quantified and made available to applicant and recognized facilities;
- b) simple method of calculating the cost of participation in the program for applicant and recognized facilities;
- c) revised invoicing procedure that will equalize annual fees payable to the SCC;
- d) equitable recovery of actual inspector travel and accommodation costs billed at the end of each on-site inspection or study audit; and
- e) clear policy regarding any refunding of fees paid to the GLP monitoring authority.

This revised GLP Fee Schedule is effective June 1, 2002.

Facilities that applied under the initial GLP fee schedule [September 1998], but have not yet received their recognition will be invoiced based on that schedule's fees and procedures for completion of their recognition process. This revised fee schedule will, however, apply upon receiving their GLP recognition.

B. COMPONENTS OF THE FEE SCHEDULE

1. Application Fee

The application fees for test facilities and field sites have been adjusted to cover the costs for initial inspection visits. Application fee revenue also recovers the costs associated with serving each applicant before the initial on-site inspection visit. This includes creating the applicant file and assigning a PALCAN Senior Program Officer (SPO) for client liaison and review of the application package.

Standards Council of Canada

A non-refundable **\$1000** portion of the application fee must be submitted with the application. Applicant GLP facilities will be invoiced 50% of the remaining application fee and the inspector(s) travel and accommodation costs upon completion of the initial inspection. The remaining 50% of the application fee will be invoiced upon receipt of GLP in-compliance recognition. **Applicant facilities will also be invoiced for their total annual fees upon receiving their GLP in-compliance recognition [see table].**

GLP facilities that are accredited pay a reduced application fee as a fee was also paid upon application for accreditation. A GLP recognized facility that is not accredited would pay an additional \$1000 on application to PALCAN should they apply to be accredited.

2. Total Annual Fees

The total annual fee is comprised of a **Base Fee**, a **PSA Fee** and a **Facility Fee**. This annual fee is charged when recognition is granted, and thereafter on the anniversary date of official recognition of the facility, regardless of whether there is an inspection scheduled that year.

a) Base Fee

This flat rate base fee (**\$500**) is charged to all GLP recognized facilities to cover administration costs, official notification of recognized status, possible study audits by special request from regulatory authorities of member countries under OECD requirements, and so on.

Accredited laboratories that are also GLP compliant facilities do not pay the base fee as this is already paid as part of their accreditation fees.

b) Program Specialty Area Fee

This PSA fee (**\$750**) is the source of funding for the obligations and initiatives that fall to SCC as a Canadian GLP Monitoring Authority, and is now the same amount paid by most PALCAN laboratories. The GLP compliance-monitoring program carries specific unique requirements. These include, but are not limited to, cooperation and coordination with the OECD Council and international GLP monitoring authorities, GLP working group meetings, and the recruiting and training of GLP inspectors.

c) Facility Fee

The SCC GLP compliance monitoring authority conducts the following routine GLP inspections:

- (i) initial complete inspections, including both a facility inspection and study audit(s) for those facilities which have previously conducted GLP studies; and
- (ii) biennial regularly scheduled complete re-inspections, including a study audit(s).

Standards Council of Canada

The facility fee covers the costs for preparation, conduct, follow-up, approval and reporting of on-site inspections for initial recognition, and for maintaining this recognition. The annual facility fee, as part of the total annual fee, represents 50% of the inspection costs for an on-site GLP inspection. GLP facilities are classified as either test facilities or field sites (test sites), and because each facility type has unique inspection requirements with respect to effort and team size, each facility type has a specific annual facility fee: **Test Facility Fee: \$2700.00 and Field Site/Test Site Fee: \$1300.00** [covering (i) and (ii) above].

Note: Sponsor organizations that are test facilities, but also have field sites, may incur an additional fee to be mutually agreed upon, during years when on-site inspections are completed. This additional supplemental fee may be required to cover additional costs to inspect their associated field site(s). The respective total annual fees for accredited laboratories is reduced by the amount of the base fee [see table].

3. Facility-Only Inspection Fee

The facility-only inspection fee is a fixed one-time fee [see table], plus travel.

Applicant facilities that are new to the principles of GLP and that have not as yet conducted GLP studies can apply for a facility-only inspection without a corresponding study audit(s). A preliminary facility-only inspection is performed to acknowledge that the necessary infrastructure is in place (facilities, equipment, staff, SOPs, QAP, archives, etc.) such as would permit the facility to successfully conduct GLP compliant studies. Applicant facilities requesting these inspections will be invoiced 50% of the remaining application fee and the inspector(s) travel and accommodation costs upon completion of the initial inspection. The remaining 50% will be payable on receipt of a letter from the SCC acknowledging that they have the necessary infrastructure in place such as would permit the facility to successfully conduct GLP compliant studies.

4. Verification Inspection Fee

The verification inspection fee is a fixed one-time fee [see table], plus travel.

Verification inspections can be scheduled, if deemed necessary, to confirm that identified GLP deviations from a previous inspection have been suitably addressed, or to follow up after a facility relocation, merger or major renovations at the facility. Facilities where a verification inspection is required are invoiced 50% of the fee and the inspector(s) travel and accommodation costs upon completion of the inspection. The remaining 50% will be payable on receipt of a letter from the SCC acknowledging that their GLP recognition is continued.

Standards Council of Canada

5. Study Audit Fee

The SCC will complete GLP study audits, a) at facilities that requested a facility-only inspection, or b) specific study audits requested by external national or international authorities.

a) The SCC study audit fee is a fixed one-time fee [see table], plus travel.

Applicant facilities requesting a facility-only inspection must request the SCC conduct a subsequent study audit once a complete study is available to fully complete the GLP recognition process. Applicant facilities requesting these study audits will be invoiced 50% of the fee and the inspector(s) travel and accommodation costs upon completion of the on-site study audit. The remaining 50% will be invoiced upon receipt of their GLP recognition from the SCC. As stated above, these applicant facilities would then also be invoiced for their total annual fees [see table] upon receiving their recognition.

b) External national or international authorities may request that the SCC GLP monitoring authority complete a specific study audit(s) at specific GLP facilities. Any associated costs are borne internally by the program and are not invoiced to the subject GLP facility.

GLP FEE SCHEDULE

FEE COMPONENT	GLP FACILITY TYPE		SCC ACCREDITED LABORATORY	
	<u>Field Site*</u>	<u>Test Facility</u>	<u>Test Site*</u>	<u>Test Facility</u>
Application Fee	\$3600	\$6400	\$2600	\$5400
Total Annual Fee	\$2550	\$3950	\$2050	\$3450
Base	\$500	\$500	NA	NA
PSA	\$750	\$750	\$750	\$750
Facility	\$1300	\$2700	\$1300	\$2700
Facility-only Inspection Fee	\$2500	\$3500	\$2500	\$3500
Verification Inspection Fee	\$2000	\$2500	\$2000	\$2500
Study Audit Fee	\$2500	\$3500	\$2500	\$3500

*Field Sites are also Test Sites.

Note: Actual travel costs for inspections/study audits are billed separately. Normally, one inspector for field sites, and two inspectors for test facilities and laboratory test sites.

Standards Council of Canada

C. REFUND OF FEES FOR APPLICANT AND RECOGNIZED GLP FACILITIES

The purpose of this section is to define the terms and conditions under which the SCC will allow refunds in whole or in part of fees paid by applicant or recognized GLP facilities.

1. Applicant GLP Facilities

The \$1000 portion of the application fee submitted with an application is non-refundable. The remaining portions of the application fee are invoiced after the initial inspection and when GLP recognition is granted. Therefore if paid, the remaining portions of the application fee are not refundable if a facility withdraws voluntarily before completing the GLP recognition process.

2. Recognized GLP Facilities

The Base fee and PSA fee portions of the Total Annual Fee are refundable on a pro-rata basis for the period from the date written notice of voluntary withdrawal is received at the SCC to the facility's anniversary date. Such voluntary withdrawal notices must be received, however, at least 30-calendar days prior to the anniversary date of GLP recognition: otherwise no portion of the Base fee or PSA fee will be refunded.

The Facility fee portion of the Total Annual Fee is totally refundable if no inspection has occurred.

There is no refund of any portion of the Total Annual Fee if a GLP recognized facility is withdrawn from the GLP program by the monitoring authority.

D. APPLICATION BY AN ACCREDITED LABORATORY

A testing laboratory accredited under PALCAN may apply at any time for GLP recognition under this PSA. Such applications will be treated as a scope extension request, and the relevant PSA fees will apply. If possible, the resulting GLP recognition will be coordinated to the laboratory's accreditation anniversary date, so that future reinspections are scheduled and conducted simultaneously with accreditation reassessment visits. Mutually agreeable arrangements for these inspections will be arranged between the SCC and the subject facility/laboratory. The same rules apply in reverse for a GLP recognized test facility that seeks PALCAN laboratory accreditation.

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E. REVIEW AND CHANGE

This GLP PSA fee schedule is subject to periodic review. Subsequent reviews will be held to ensure that the fees continue to accurately reflect the costs experienced by the SCC, and to ensure compliance with PALCAN fee schedules and SCC finance policy and procedures.

F. FURTHER INFORMATION

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