Life Sciences & Pharmaceutical Industry

The following guidelines are intended to provide examples of "experimental development" projects which would qualify for Canadian SR&ED (Scientific Research & Experimental Development) tax credits.

Content Summary:

901 - Hun-Medipharma - Eligibility of analysis without clinical trials:

Scientific or Technological Objectives:

Measurement	Current Performance	Objective
SR&ED eligibility (%)	0	100

FACTS:

The appeal examined two separate projects: Project 1/b - Anti-stress Tablet (for human use) & Project 2: Medical Skin Care Products (for human use).

[AUTHOR'S NOTE: THIS APPEAL CONCERNS SR&ED EXPENSES FOR THE 1994 TAXATION YEAR. IT IS ONE OF THE FEW SR&ED TAX CASES WHICH WENT THROUGH UNDER THE INFORMAL APPEAL PROCESS WHICH TYPICALLY REQUIRES THAT THE AMOUNTS IN DISPUTE BE LESS THAN $12,000 (FOR ADDITIONAL DETAILS SEE TAX COURT OF CANADA ACT, SECTION 18.). IN THIS CASE THE EXPENDITURES NOT QUALIFIED FOR ITC WERE $5,165 WITH A RELATED REDUCTION IN FEDERAL ITC'S OF $5,165 X 35%= $1,808.]

Technology or Knowledge Base Level:

Benchmarking methods & sources for citings:

- Similar prior in-house technologies: 2 products / processes -- two separate projects: Project 1/b - Anti-stress Tablet & Project 2: Medical Skin Care

MAIN ISSUES:

The CRA science auditor's major concern with both projects is that they "consisted only of a review of the literature on a certain subject in the preparation for a DIN [drug submission] application to HPB [Health Protection Branch]. Also, there were no clinical trials conducted," although she admitted that there, "was conceptual work done on the project."

Field of Science/Technology:

Pharmacology and pharmacy & medicinal chemistry (3.01.05)

Intended Results:

- Improve existing processes
- Improve existing materials, devices, or products

Scientific or Technological Advancement:

Uncertainty #1: SR&ED = Experimentation &/OR Analysis?

The primary issue of this case might be summarized as, whether the legal definition of SR&ED requires the scientific research and experimental development to be carried out by "experiment and analysis" or merely by "analysis."

The most significant underlying key variables are:
analysis of data, experimentation

Activity #1-1: Are clinical trials required (or just analysis)?

Work performed in Fiscal Year 2009:

Methods of experimentation:

- Analysis / simulation: 2 alternatives - "or" and "and"

A. the CRA Science auditor's major concern with both projects:

Though the science auditor in this case did not doubt the claimant's technical credentials, she rejected the project for the Anti-Stress Tablet because it "consisted only of a review of the literature on a certain subject in the preparation for a DIN [drug submission] application to HPB [Health Protection Branch]. Also, there were no clinical trials conducted."

B. Additional details submitted with respect to Project 1/b - Anti-stress Tablet (for human use):

The taxpayer explained that, "the data had been gathered in Germany for the use of a drug used for a certain purpose. Their intended purpose was different and that the analysis was for that purpose." The taxpayer allegedly produced further documents to evidence the fact that the analysis was systematic and that the, "work completed was for the analysis of data for the advancement of medical sciences."

The judge then reviewed the legal definition of SR&ED [then paragraph 2900(1) of the regulations now subsection 248(1)] and compared the work in question.

Results:

- SR&ED eligibility: 100 % (100% of objective)

Conclusion:

In the judge's opinion, the fact that the taxpayer did not conduct clinical trials in this case was not considered enough to negate the eligibility of the work since, in the judge's opinion the wording of the legislation, "does not require that systematic investigation be made by both experiment and analysis. It can be made by experiment or analysis, provided it is in fact a systematic investigation."

Key variables resolved: analysis of data, experimentation

901 - Hun-Medipharma - Eligibility of analysis without clinical trials

Benchmarks: Similar prior in-house technologies: 2 products / **Objectives:** SR&ED eligibility: 100 %

Uncertainty: 1 - SR&ED = Experimentation &/OR Analysis? **Key Variables:** analysis of data, experimentation

Activity	Testing Methods	Results - % of Objective	Variables Concluded	Hours	Materials $	Subcontractor $	Fiscal Year
1 - Are clinical trials required (or just analysis)?	Analysis / simulation: 2 alternatives	SR&ED eligibility: 100 % (100 %)	analysis of data experimentation	0.00	0.00	0.00	2009

Project Details:

Scientific or Technological Objectives:

Measurement	Current Performance	Objective
DOC reduction (%)	0	20
Maximize the rate of organic contaminant removal (%)	50	95
Minimize variations in operating conditions (%)	30	10
maximum cost of study ($)	0	5500

[AUTHOR'S NOTE: IDEALLY THE TAXPAYER WOULD ATTEMPT TO QUANTIFY THE OBJECTIVES THEY ARE TRYING TO ACHIEVE. A QUANTIFIABLE OBJECTIVE HAS BEEN ADDED ABOVE, TO ILLUSTRATE.]

The objective of this project was to determine the appropriate flow rates of oxygen (350 - 500 liters/min) and influent (100 - 150 liters/min.) required to maximize the rate of organic contaminant removal in the bio-reactor unit, while monitoring the effects of normal variations in operating conditions (pH, temperature, waste stream composition) on the system.

Technology or Knowledge Base Level:

Benchmarking methods & sources for citings:

- Internet searches: 17 sites / articles -- no solution found
- Patent searches: 3 patents -- different environments
- Similar prior in-house technologies: 1 products / processes -- We have experience with this system, but want to further improve performance.
- Queries to experts: 7 responses -- engineers have shown understanding by reducing DOC levels in the process wastewater by up to 50 %

[NOTE: THIS EXAMPLE IS REPRODUCED FROM THE SR&ED GUIDANCE DOCUMENT ENTITLED: "CHEMICALS GUIDANCE DOCUMENT #3 - PART I - CHEMICAL PROCESSES", DEVELOPED BY A CHEMICALS INDUSTRY & CANADA REVENUE AGENCY (CRA) JOINT COMMITTEE].

The company has gained significant knowledge about treating typical waste streams after several years of operation of a biological wastewater treatment system. Optimizing pH, temperature and low-pressure airflow has controlled dissolved organic carbon and key contaminants in the waste stream. The company's engineers have shown their understanding by reducing DOC levels in the process wastewater by up to 50%. Despite these successes, there remains a great deal that is not known about the effect of operating conditions such as rates and type of oxygen feed.

Field of Science/Technology:

Bioremediation (2.08.02)

Intended Results:

- Improve existing processes

Work locations:

Commercial Facility

902 - Bio-treatment of Wastewater:

Uncertainty #1: Replacing the low pressure air feed with oxygen

The company sought to advance the waste bio-treatment process by replacing the low pressure air feed with oxygen. The company's rationale was that, by using pure oxygen to enhance bioactivity and by eliminating the other gases present in air, the level of organic compounds in the waste stream and the rate of volatile emissions from the system would both be reduced. It was technologically unclear, however, if the removal of the other gases might interfere with some of the degradation processes.

The most significant underlying key variables are:

level of organic compounds, rate of volatile emissions, Optimizing pH, temperature and low-pressure airflow

Activity #1-1: Installation of pure oxygen supply

Work performed in Fiscal Year 2009:

Methods of experimentation:

- Physical prototypes: 1 samples

  Work was completed on the installation of a pure oxygen supply to the bioreactor. Engineering work was completed to install baffles that would maximize mixing within the reactor.

Results:

- DOC reduction: 10 % (50% of objective)
- Maximize the rate of organic contaminant removal : 55 % (11% of objective)
- Minimize variations in operating conditions : 25 % (25% of objective)

Conclusion:

[PLACE CONCLUSION HERE]

Key variables resolved: level of organic compounds, Optimizing pH, and rate of volatile emissions, temperature and low-pressure airflow

Activity #1-2: Optimization of oxygen supply and

Work performed in Fiscal Year 2009:

Methods of experimentation:

- Process trials: 12 runs / samples - Each trial ran 5 days. Varied oxygen flow and influent addition.

  A Statistical Experimental Design (SED) was developed using a commercially available software package. A number of responses were measured in a series of twelve trials in which the oxygen flow (5 levels between 300 and 500 L/min) and rate of influent addition (5 levels between 100 and 150 L/min) were varied. This is a response surface design quadratic model, which will allow estimation of linear, interaction and quadratic terms, and can be applied to all responses measured. The results allowed for modeling of the system and optimization of the two rate parameters for each response variable tested.

  To allow for equilibration of the biological system and to include normal variations in waste stream composition, each individual trial was conducted for a period of 5 days. To accommodate process changes between trials, the entire SED was completed over a period of twelve weeks. During each of the trials, levels for DOC, VOC, TKN and selected contaminants in the effluent stream were monitored daily as indicators of contaminant reduction. Dissolved oxygen, temperature, oxygen uptake and pH were also monitored daily as key indicators of biological activity.

Results:

- DOC reduction: 18 % (90% of objective)
- Maximize the rate of organic contaminant removal : 90 % (88% of objective)

Conclusion:

The determination of the level of selected contaminants in the wastewater was beyond the capability of the in-house laboratory and this work was contracted out to a Canadian environmental laboratory at a cost of $75 per sample. Samples were collected in duplicate and shipped to the lab on a daily basis. Operators were responsible for the daily sampling of each trial. This work was completed as a separate activity by operators and was done in addition to regular quality control sampling.

Key variables resolved: level of organic compounds, Optimizing pH, and rate of volatile emissions, temperature and low-pressure airflow

Activity #1-3: Analysis of Results

Work performed in Fiscal Year 2010:

Methods of experimentation:

- Analysis / simulation: 3 alternatives

  The experimental results were analyzed with the help of the statistical software package used in setting up the SED. This package allowed for the development of mathematical models to determine the optimal conditions for compound destruction, minimization of volatile emissions and the enhancement of biological activity in the bioreactor system.

Results:

- DOC reduction: 20 % (100% of objective)
- Maximize the rate of organic contaminant removal : 95 % (100% of objective)

Conclusion:

This model showed that a rate of pure oxygen addition of 425 L/min. and an influent rate of 120 L/min. would provide optimal biological activity and maximum reduction in the key contaminant characteristics studies. At these optimum rates, the bioreactor

could treat 15% more waste and achieve a 20% reduction in DOC and TKN, and reduce VOCs and contaminants of concern to below detectable levels.

Key variables resolved: level of organic compounds, Optimizing pH, and rate of volatile emissions, temperature and low-pressure airflow

Activity #1-4: Verification of Model Prediction

Work performed in Fiscal Year 2010:

Methods of experimentation:

- Process trials: 1 runs / samples - Week-long trial to verify model.

  An additional one-week trial was conducted with the optimal flow rates of oxygen and influent rates that the model predicted. The one-week trial allowed for the establishment of equilibrium in the system and verification of the model.

Results:

- Maximize the rate of organic contaminant removal : 95 % (100% of objective)
- Minimize variations in operating conditions : 11 % (95% of objective)
- maximum cost of study: 6000 $ (109% of objective)

  Results of the trial confirmed both the enhanced biological activity and the reductions in DOC, TKN, VOC and contaminant levels.

Conclusion:

The results demonstrated that it was possible to increase degradation of the organic waste.

Key variables resolved: level of organic compounds, Optimizing pH, and rate of volatile emissions, temperature and low-pressure airflow

902 - Bio-treatment of Wastewater

Benchmarks: Internet searches: 17 sites / articles
Patent searches: 3 patents
Similar prior in-house technologies: 1 products /
Queries to experts: 7 responses

Objectives: DOC reduction: 20 %
Maximize the rate of organic contaminant removal : 95 %
Minimize variations in operating conditions : 10 %
maximum cost of study: 5500 $

Uncertainty: 1 - Replacing the low pressure air feed with oxygen

Key Variables: level of organic compounds, Optimizing pH, rate of volatile emissions, temperature and low-pressure airflow

Activity	Testing Methods	Results - % of Objective	Variables Concluded	Hours	Materials $	Subcontractor $	Fiscal Year
1 - Installation of pure oxygen supply	Physical prototypes: 1 samples	DOC reduction: 10 % (50 %) Maximize the rate of organic contaminant removal : 55 % (11 %) Minimize variations in operating conditions : 25 % (25 %)	level of organic compounds Optimizing pH rate of volatile emissions temperature and low-pressure airflow	0.00	0.00	0.00	2009
2 - Optimization of oxygen supply and	Process trials: 12 runs / samples	DOC reduction: 18 % (90 %) Maximize the rate of organic contaminant removal : 90 % (88 %)	level of organic compounds Optimizing pH rate of volatile emissions temperature and low-pressure airflow	0.00	0.00	0.00	2009
3 - Analysis of Results	Analysis / simulation: 3 alternatives	DOC reduction: 20 % (100 %) Maximize the rate of organic contaminant removal : 95 % (100 %)	level of organic compounds Optimizing pH rate of volatile emissions temperature and low-pressure airflow	0.00	0.00	0.00	2010
4 - Verification of Model Prediction	Process trials: 1 runs / samples	Maximize the rate of organic contaminant removal : 95 % (100 %) Minimize variations in operating conditions : 11 % (95 %) maximum cost of study: 6000 $ (109 %)	level of organic compounds Optimizing pH rate of volatile emissions temperature and low-pressure airflow	0.00	0.00	0.00	2010