Technology for the management of Biosafety

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Background

Set of scientific-organizational and technical-engineering measures designed to protect the worker of the facility, the community and the environment from the risks involved in working with biological agents, or the release of organisms into the environment, minimize the effects that may arise and quickly liquidate their possible consequences in case of contamination, adverse effects, escapes or losses (Decree Law 190, 1999).
Decree Law 190

Biosafety’s Resolutions

TS 573: 2007

Biosafety Inspection Manual, Biosafety Program.
Basic Requirements

teaching, research, biotechnology
Main goal

To develop a technology for the organization of Biological Safety
Materials and Methods

Characterization of Biological Safety

Culture of Biological Safety (Hernández, 2008)
Perception of biological risk (Torres, 2013)

Moderate Risks
Specific causes

Technology

Commitment, compliance with the legal framework, strategic conception and viability of resources
<table>
<thead>
<tr>
<th>Variable</th>
<th>Questions</th>
<th>Possible answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiarity</td>
<td>1. Have you received basic training on Biological Safety? (Q1)</td>
<td>No/very little/ enough</td>
</tr>
<tr>
<td></td>
<td>2. How long you have been in this job? (Q2)</td>
<td>1 year, 1 a 5 years, more than 5 years</td>
</tr>
<tr>
<td></td>
<td>3. Have you received specific training related with biological risk in this job? (Q3)</td>
<td>No/very little/ enough</td>
</tr>
</tbody>
</table>
Materials and Methods

Characterization of Biological Safety

Culture of Biological Safety (Hernández, 2008)

Perception of biological risk (Torres, 2013)

Moderate Risks

Specific causes

Technology

Commitment, compliance with the legal framework, strategic conception and viability of resources
CIBHO: From September 2008 to September 2010
CIRAH: From January 2012 to September 2014
Results and Discussion
Figure 1. Conceptual model for the organization of Biological Safety
Figure 2. Conceptual model by Cooper, 1995
## Procedure

<table>
<thead>
<tr>
<th>Characterization of Biological Safety</th>
<th>Organization of Biological Safety and Biosecurity</th>
<th>Application of Biological Safety’s documentation</th>
<th>Technology evaluation through the analysis of indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Selection of indicators</td>
<td>1. Definition of Biological Safety policy</td>
<td>1. Implementation of Biological Safety’s documents</td>
<td></td>
</tr>
<tr>
<td>2. Analysis of indicators</td>
<td>2. Organization chart of Biological Safety</td>
<td>2. Staff evaluation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. General procedures of Biological Safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Specific procedures of Biological Safety</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Characterization of Biological Safety in CIBHO

Table 1. First Qualification. Aspects and Culture of Biological Safety

<table>
<thead>
<tr>
<th>Aspects</th>
<th>Management status</th>
<th>Quantitative</th>
<th>Qualitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Policy</td>
<td>2,65</td>
<td>Fragile</td>
<td></td>
</tr>
<tr>
<td>2. Organization chart of Biological Safety</td>
<td>3,12</td>
<td>Adequate</td>
<td></td>
</tr>
<tr>
<td>3. Materials resources</td>
<td>2,24</td>
<td>Fragile</td>
<td></td>
</tr>
<tr>
<td>4. Self-regulation</td>
<td>3,71</td>
<td>Adequate</td>
<td></td>
</tr>
<tr>
<td>5. Definition and Control</td>
<td>2,59</td>
<td>Fragile</td>
<td></td>
</tr>
<tr>
<td>6. Responsibilities</td>
<td>3,71</td>
<td>Adequate</td>
<td></td>
</tr>
<tr>
<td>7. Training</td>
<td>2,65</td>
<td>Fragile</td>
<td></td>
</tr>
<tr>
<td>8. Premium and sanctions</td>
<td>1,12</td>
<td>Unsafe</td>
<td></td>
</tr>
<tr>
<td>9. Audit, exam and comparison</td>
<td>3,76</td>
<td>Adequate</td>
<td></td>
</tr>
<tr>
<td>10. Critical attitude</td>
<td>2,35</td>
<td>Fragile</td>
<td></td>
</tr>
<tr>
<td>11. Rigorous approach</td>
<td>2,29</td>
<td>Fragile</td>
<td></td>
</tr>
<tr>
<td>12. Communication</td>
<td>2,82</td>
<td>Fragile</td>
<td></td>
</tr>
</tbody>
</table>

Culture of Biological Safety: 2.75

Developing
Initial perception of biological risk: 1.7

Figure 3. Perception of biological risk by variable and average in CIBHO
Table 2. Number of risks assessed: 77 biological risks (22 moderate, 47 tolerable y ocho trivial)

<table>
<thead>
<tr>
<th>Processes</th>
<th>Moderate risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtaining bovine blood</td>
<td>1</td>
</tr>
<tr>
<td>Obtaining hidrolyzing material</td>
<td>2</td>
</tr>
<tr>
<td>Obtaining rabbit blood</td>
<td>3</td>
</tr>
<tr>
<td>Obtaining blood sheep</td>
<td>2</td>
</tr>
<tr>
<td>Scrubbing and treatment of glassware</td>
<td>7</td>
</tr>
<tr>
<td>Bovine blood sterility test</td>
<td>1</td>
</tr>
<tr>
<td>Sheep blood sterility test</td>
<td>1</td>
</tr>
</tbody>
</table>
Specific causes

Inadequate individual protection

Breach of the rules of conduct
# Characterization of Biological Safety in CIRAH

Table 3. First Qualification. Aspects and Culture of Biological Safety

<table>
<thead>
<tr>
<th>Aspects</th>
<th>Management status</th>
<th>Quantitative</th>
<th>Qualitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Policy</td>
<td></td>
<td>1,25</td>
<td>Unsafe</td>
</tr>
<tr>
<td>2. Organization chart of Biological Safety</td>
<td></td>
<td>1,83</td>
<td>Unsafe</td>
</tr>
<tr>
<td>3. Materials resources</td>
<td></td>
<td>1,75</td>
<td>Unsafe</td>
</tr>
<tr>
<td>4. Self-regulation</td>
<td></td>
<td>2</td>
<td>Fragile</td>
</tr>
<tr>
<td>5. Definition and Control</td>
<td></td>
<td>1,67</td>
<td>Unsafe</td>
</tr>
<tr>
<td>6. Responsibilities</td>
<td></td>
<td>1,92</td>
<td>Unsafe</td>
</tr>
<tr>
<td>7. Training</td>
<td></td>
<td>1,67</td>
<td>Unsafe</td>
</tr>
<tr>
<td>8. Premium and sanctions</td>
<td></td>
<td>1</td>
<td>Unsafe</td>
</tr>
<tr>
<td>9. Audit, exam and comparison</td>
<td></td>
<td>1</td>
<td>Unsafe</td>
</tr>
<tr>
<td>10. Critical attitude</td>
<td></td>
<td>2,83</td>
<td>Fragile</td>
</tr>
<tr>
<td>11. Rigorous approach</td>
<td></td>
<td>3,83</td>
<td>Adequate</td>
</tr>
<tr>
<td>12. Communication</td>
<td></td>
<td>3,08</td>
<td>Adequate</td>
</tr>
</tbody>
</table>

| Culture of Biological Safety    |                   | 1,99         | Incipient   |
Initial perception of biological risk: 1,7

Figure 4. Perception of biological risk by variable and average in CIRAH

Table 4. Number of risks assessed: 42 biological risks (24 moderate, 13 tolerable and four trivial)

<table>
<thead>
<tr>
<th>Processes</th>
<th>Moderate risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling</td>
<td>5</td>
</tr>
<tr>
<td>Isolation of DNA</td>
<td>9</td>
</tr>
<tr>
<td>Neurological studies</td>
<td>2</td>
</tr>
<tr>
<td>Scrubbing and treatment of glassware</td>
<td>8</td>
</tr>
</tbody>
</table>

Specific causes: Inadequate individual protection and breach of the rules of conduct
Stage II. Organization of Biological Safety and Biosecurity with four steps:

1. Definition of Biological Safety policy
2. Organization chart of Biological Safety
Figure 5. Organization chart Biological Safety in CIBHO
Figure 6. Organization chart Biological Safety in CIRAH
Stage II. Organization of Biological Safety and Biosecurity with four steps:

3. General procedures of Biological Safety

- Risk Assessment
- Biological Safety Inspection
- Emergency’s procedures
- Medical control of the Staff
- Vector surveillance and control
- Hazardous waste Management
- Safety Standards: Biological Safety and Occupational Safety and Health Administration were integrated
Stage II. Organization of Biological Safety and Biosecurity with four steps:

4. Specific procedures of Biological Safety

CIBHO

- Waste treatment and destructions
- General use of equipments
- Production’s Processes: disinfection, hazardous waste, emergency management and safety measurements
Stage II. Organization of Biological Safety and Biosecurity with four steps:

4. Specific procedures of Biological Safety

CIRAH

Procedures for biological risk’s processes: 39
• Obtaining, receiving and transportation of samples
• DNA Isolation
• Storage, conservation and use of samples in DNA Bank
• Processing and analysis of neurological tissues
Stage III. Application of Biological Safety’s documentation and Biosecurity with two steps:

1. Implementation of Biological Safety’s documents
2. Staff evaluation

The score:
CIBHO: 80 and more
CIRAH: 85 and more
• Stage IV. Technology evaluation through the analysis of the indicators

Figure 7. Comparison of the aspects of the Culture of Biological Safety. CIBHO. Before and after.
Culture of Biological Safety. CIBHO: In development to Consolidated

Figure 8. Matrix of the Culture of Biological Safety. CIBHO.
Biological risk profile by perception variables once the technology is implemented. CIBHO

Figure 9. Perception of biological risk by variable and average in CIBHO after the technology
Figure 10. Perception of biological risk by variable and average in CIBHO before and after the technology
Figure 11. Comparison of the aspects of the Culture of Biological Safety. CIBHO. Before and after.
Culture of Biological Safety. CIRAH: Incipient to On take off

Figure 12. Matrix of the Culture of Biological Safety. CIRAH.
Biological risk profile by perception variables once the technology is implemented. CIRAH

Figure 13. Perception of biological risk by variable and average in CIRAH after the technology

Figure 14. Perception of biological risk by variable and average in CIRAH before and after the technology
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiarity (FAMI)</td>
<td>Indirect</td>
<td>CIBHO: 2,36</td>
<td>2,08</td>
<td>1,86</td>
<td>CIBHO: 1,11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CIRAH: 2,3</td>
<td></td>
<td></td>
<td>CIRAH: 1,43</td>
</tr>
<tr>
<td>Accident history (HIST)</td>
<td>Direct</td>
<td>CIBHO: 1</td>
<td>1,03</td>
<td>2,27</td>
<td>CIBHO: 2,3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CIRAH: 1</td>
<td></td>
<td></td>
<td>CIRAH: 1,6</td>
</tr>
</tbody>
</table>
Figure 15. Moderate biorisks in CIBHO and CIRAH before and after the technology
Specific causes
Conclusions

1. The technology conformed by a conceptual model of Biological Safety and its procedure with a process and risk based approach allowed the integration of Biosecurity into the processes of the organization to contribute to the reduction of biological risk, as well as to the prevention and promotion of health in the work scenario.
Conclusions

2. The selected indicators had a direct impact on the reduction of biological risk due to their action on changes in the behavior of personnel exposed to this type of risk and contribute to the prevention and promotion of health in the workplace.
Conclusions

3. The implementation of the technology in the CIBHO and the CIRAH made it possible to place Biological Safety on a higher plane, raise the quality of the products and services generated there and to prevent and promote health in the workplace.
Recommendations

Expand in the proposed technology the content referring to the Biosecurity as an element of the model to achieve a better protection of the worker, the community and the environment.
Technology for the management of Biosafety

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Publications


- Culture of Biological Safety as a basic tool for the design of biosecurity documents. *Revista Cubana de Higiene y Epidemiología* 2015; 53 (2).

- Methodology implementation in order to evaluate the biological risks in the Centre for Research and Rehabilitation of Hereditary Ataxias of Cuba. A biosecurity surveillance method. *Medicina y Seguridad del Trabajo* 2014; 60 (237) 620-626.

- General elements on zoonoses. *Correo Científico Médico* ISSN 1560-4381 CCM 2014; 18 (4).
Publications

- Biological safety in the health sector. Point of view. *Correo Científico Médico* ISSN 1560-4381 CCM 2013; 17 (2).

- Biological risk management in the Center of Immunology and Biopreparados of Holguin (summary). *Correo Científico Médico* ISSN 1560-4381 2012; 16(3) Supl 1.

- Basic aspects of the pathogenesis, immune response and Biosafety in the work with *Toxoplasma gondii*. *Correo científico médico*. CCM 2012 16 (1). ISSN 1560-4381.


Registro Facultativo de Obras Protegidas y de Actos y Contratos referidos al Derecho de Autor

CERTIFICACION DE REGISTRO

Licenciada Lily Massiel Sarro Acé, funcionaria encargada del Registro Facultativo de Obras Protegidas y de Actos y Contratos referidos al Derecho de Autor.

CERTIFICO:

Que la obra cuyos datos se consignan a continuación, aparece inscrita en el referido Registro con el número: 1241-04-2018.

Título: Desarrollo de un modelo conceptual para la organización de la Seguridad Biológica en dos entidades de salud de Holguín.

Tipo de Obra: Literario.

Breve descripción de la obra: La obra es una investigación que desarrolla un modelo conceptual para organizar la Seguridad Biológica con enfoque basado en sistema, proceso y riesgo. Se aplicó en dos entidades de salud de Holguín y se muestran los resultados obtenidos en las mismas que tratan de la prevención y promoción de la salud en el ambiente laboral.

Autores: Daisís Cobos Valdés,
Mayra Ramos Lima

Títulare: Centro de Inmunología y Bioestereodidos de Holguín,
Centro para la Investigación y Rehabilitación de las Ataxias Hereditarias de Holguín.

Dada en La Habana, a los 23 días del mes de abril de 2018.

[Se firma]

[Se firma]

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