gapiii CONTAINMENT cERTIFICATION

COST (MAN-day) calculation guidance

A key component in the implementation of the CCS will be the need for audits in different countries and in association with a variety of facility types, to be conducted in a fair and equitable manner. It will be essential to ensure that the effort applied in assessments of the different PEFs is reasonable, proportionate, and consistent. The aim of this guidance is to provide information as to what might be expected in planning and conducting audits in relation to potential duration and associated cost, described in terms of man-days. The aim is not to prescribe fixed time allocations, but rather to propose a framework within which PEFs and NACs can demonstrate that appropriate resources are being applied in the conduct of CCS audits and related activities.

Although there will be additional administrative areas that will need to be resourced by NACs in maintenance of their role in relation to the CCS (e.g. the preparation and maintenance of certification procedures and oversight of auditor competence), this guidance specifically addresses audit planning, execution and follow-up.

***Initiation and planning***

This will largely be conducted by the team leader. However, other team members may also be required to provide input to the schedule, discuss focus areas, review documents, etc. Although the primary focus of this guidance is time on site, provision for adequate preparation should also be made. No specific time allocation is proposed for this activity as this will be at least partly dependent on the nature of the facility, the need for up-front document review, together with the familiarity of the audit team with the facility and other factors. However, this area should be formally addressed and information presented as part of certification reports to the GCC in order to demonstrate that adequate planning did take place, including allocation of adequate resource.

***Performance***

This is a highly subjective area and required effort will be based on a number of factors, including the size, scale, complexity, and physical location/layout of the facility/facilities. As an approximate guide, for the first full scope audit, approximately one half day should be allocated for each biorisk management element described in GAPIII, Annex 2 and Annex 3. How this effort is allocated may vary based on circumstances and will depend on the major focus areas and relative complexity and volume of the respective elements, but this should allow sufficient time for document review, interviews with personnel, facility tours and associated verification activities. To fully assess against the elements without in-depth prior knowledge of the facility and biorisk management system, it is estimated that a full scope audit would require approximately 8 man-days of effort to review all elements. However, time should also be allocated for attendance at opening/closing meetings, team meetings, formulation of findings and other relevant activities. Again, this will vary depending on the nature and number of issues to be discussed, but would normally be considered to constitute a minimum of a further half day per team member.

***Reporting and follow-up***

This activity will be under the responsibility of the team leader and will vary with the number and type of findings. This would normally require a minimum of one additional man-day, but could necessitate more time depending upon the nature and volume of findings and associated action plans, together with the need to discuss and verify NCs, some of which may require an additional site visit which would be in addition to the time allocations associated with the initial certification visit.

***Considerations***

There may clearly be a variety of factors that could either increase or reduce the man-days required for a CCS audit, including:

Increased

1. The system covers highly complex processes or a relatively high number of unique activities.
2. Complicated logistics involve very large sites and/or more than one site or building where work is carried out.
3. Need for translation of spoken and written information.
4. High degree of national regulation.
5. Other additional relevant factors (e.g. need to cover multiple shifts).

Decreased (Note: maximum reduction 30%)

1. Not all elements covered in scope.
2. Maturity of management system and familiarity/experience from previous assessments.
3. Auditee preparedness for certification (e.g. already certified to another similar or equivalent standard recognized by another third party scheme, including CWA 15793).
4. Low complexity activities including those involving a single generic activity (e.g. storage in a secure repository).
5. Other additional relevant factors.

Man-day effort, including any specific considerations leading to either significantly increased or decreased man-days should be indicated in the audit report submitted to the GCC. Failure to present a justifiable man-day calculation may jeopardize GCC’s endorsement of a containment certificate.

***Example agenda***

A specimen agenda for a full scope initial audit is presented below. The assignment of team members to the different interviews will contribute to calculating the man-days for the audit.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Team 1** | **Interviewees** | **Team 1 members** | **Team 2** | **Interviewees** | **Team 2 members** |
| **Monday** |  |  |  |  |  |  |
| 0900 - 0930 | Opening meeting | Management and All Involved | All |  |  |  |
| 0930 - 1200 | Document review, orientation and site tour |  |  |  |  |  |
| Lunch |  |  |  |  |  |  |
| 1300 - 1600 | Biorisk Management System |  |  |  |  |  |
| 1630 - 1700 | Summary and review |  |  |  |  |  |
| **Tuesday** |  |  |  |  |  |  |
| 0900 - 1200 | Risk Assessment |  |  | Good Microbiological Techniques |  |  |
| Pathogen Inventory |  |  |
| Lunch |  |  |  |  |  |  |
| 1300 - 1430 | Disinfection, Decontamination and Sterilisation |  |  | Emergency Response and Contingency Plans |  |  |
| 1430 - 1600 | Clothing and PPE |  |  | Accident/Incident Investigation |  |  |
| 1630 - 1700 | Summary and review |  |  |  |  |  |
| **Wednesday** |  |  |  |  |  |  |
| 0900 - 1030 | Personnel and Competency |  |  | Transport Procedures |  |  |
| 1030 - 1200 | Healthcare |  |  | Security |  |  |
| Lunch |  |  |  |  |  |  |
| 1300 - 1430 | Equipment and Maintenance |  |  | Human Factors |  |  |
| 1430 - 1600 | Facility Physical Requirements |  |  | General Safety |  |  |
| 1630 - 1700 | Summary and review |  |  |  |  |  |
| **Thursday** |  |  |  |  |  |  |
| 0900 - 1200 | Facility visits |  |  | Facility visits |  |  |
| 1300 - 1600 | Facility visits |  |  | Facility visits |  |  |
| **Friday** |  |  |  |  |  |  |
| 0900 - 1200 | Verifications / presentation preparation |  |  |  |  |  |
| Lunch |  |  |  |  |  |  |
| 1300 - 1400 | Close-out Presentation | Management and All Involved |  |  |  |  |