



Installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API), and the installation of LPG storage tanks in a facility/factory already covered by permit PA 04236/08

At, Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa.

TERMS OF REFERENCE

FOR THE PREPARATION OF AN

ENVIRONMENTAL IMPACT STATEMENT

29-November-2012

DISCLAIMER:

1. The eventual assessment shall in no way be constrained or conditioned by the content, structure, or limitations of this document, and MEPA reserves the right to amend the TORs, even significantly, as necessary. Such amendments may include: additional studies or extension of studies; omission or downscaling of any studies deemed irrelevant or unimportant; changes to methodology, format or level of detail; and any other modifications as MEPA deems appropriate once a clearer picture of the proposal is available. The content of this document shall in no way constitute an exemption from the ensuing requirements, nor shall MEPA be responsible or liable for any issues, difficulties or claims arising from variations from this document.
2. EIA Terms of Reference are primarily intended to guide the EIA process, rather than as a basis for tendering, subcontracting, calls for expression of interest, or other purposes even if ancillary to the project. Any use for such purposes is at the sole risk of the user.

- Note 1:** The Malta Environment and Planning Authority (MEPA) reserves the right to modify these Terms of Reference according to any relevant environmental and planning considerations that may emerge at any relevant stage of the EIA or the permit application process, as well as in the event of any changes or updates to the proposed development. MEPA also reserves the right to request additional or amended studies should the findings of the EIA be insufficient to adequately inform the decision-making process or if the EIA identifies matters which should be subject to further investigation.
- Note 2:** Unless otherwise agreed with MEPA, all requirements set out in these Terms of Reference are to be complied with. If there are any aspects that the consultants deem irrelevant to this study, or if at any stage the consultants discover any environmentally-relevant aspect (not included in these TORs) that needs to be studied, the consultants shall inform MEPA immediately, justifying their reasoning.
- Note 3:** Difficulties, including technical difficulties and lack of information, encountered by the consultants in compiling the required information shall be made clear in the EIA. All references to published works and sources of information shall be duly acknowledged in a manner that enables tracing of the information source and verification. No material may be incorporated by reference unless it is reasonably available for inspection by potentially interested persons within the consultation period and thereafter, and for record-keeping and unhindered perusal by MEPA. Any material which is based on unavailable proprietary data shall not be incorporated by reference.
- Note 4:** Any requirement for confidentiality of any section or detail of the EIA must be strongly justified and a formal request in this regard must be submitted to MEPA. Should MEPA grant confidentiality, alternative material that is still adequate for proper assessment, public consultation and decision-making must be provided.
- Note 5:** Agreement on method statements, and ancillary liaison with MEPA, is not mandatory but is recommended. Nevertheless, MEPA reserves the right to disagree with the methodology proposed, including proposed areas of influence, and with the EIA submissions in general, and to factor such disagreement in its critique of the EIA.
- Note 6:** During review of the EIA, MEPA will submit comments for the consultants' consideration, as relevant. Following the consultants' response to MEPA satisfaction, a revised second draft of the EIA, addressing the comments, will normally be required. This may take the form of a complete resubmission or of an Addendum detailing the revisions to the previous submissions, as deemed most expedient by MEPA, taking into account continuity and traceability of the information, and overall user-friendliness vis-à-vis subsequent review, presentation, public consultation, record-keeping and decision-making. A complete resubmission will generally be required if changes are numerous or complex, whereas an Addendum may be preferred if changes are more limited.
- Note 7:** The consultants are not exonerated from obtaining any formal authorisation from MEPA, and from other relevant entities, vis-à-vis any activity ancillary to the EIA (e.g. collection, sampling, capture, or waiver of access restrictions) wherever such authorisation is legally required.
- Note 8:** These Terms of Reference, and all ancillary correspondence, are issued without prejudice to the Environment Protection Directorate's position on the project and to MEPA's final decision. Accordingly, their issuing (even when customised to address specific project details) should not be construed as evidence in favour or against the project or any component thereof, unless the contrary is clearly stated.

An Environmental Impact Statement (EIS) is to be prepared as required by the Environmental Impact Assessment Regulations. The required components of the EIS are:

- i. A **Coordinated Assessment Report**, in conformity with the following Sections of these Terms of Reference. This report should assess the project in its totality;
[Note: The coordinated assessment should seek to analyse and integrate the main considerations emerging from the technical reports, rather than just reproducing excerpts from the reports.]
- ii. A separate **Appendix (or Appendices)** containing all original survey reports as prepared by the individual specialist consultants for specific topics;

[Note: Experts contributing to the EIS should be specifically asked to consider impact interactions and cross-cutting issues and to communicate information between each other accordingly].

- iii. A separate **Non-Technical Summary** of the EIS, in both the Maltese and English languages. This should have enough details for the public to understand the project and the related environmental considerations, and should be written in reader-friendly language (e.g. avoiding unnecessary technical jargon);
- iv. A **declaration of conformity** with sub-regulations 28 and 29 of the EIA Regulations (refer to Appendix 1 to these Terms of Reference); and
- v. An **Addendum** detailing the **feedback received from stakeholders, from the public, and from MEPA** during the relevant consultation stages of the EIA, and how they were addressed.

Wherever relevant and appropriate, all components of the EIS should include tables and figures (e.g. maps, plans, photographs, photomontages, charts, graphs, diagrams, cross-sections) and quantifications.

The complete EIS (including all the above components) shall be submitted as a printable digital copy (in .pdf format, with copying fully enabled throughout) and as a printed copy. Likewise, once the EIS has been certified, both a printable digital copy (in .pdf format, with copying enabled throughout) and a printed copy of the certified document are to be submitted to MEPA.

Wherever any other study not forming part of the EIS (e.g. Appropriate Assessment or Feasibility Study) is also envisaged, this is to be submitted separately from the EIS. Cross-referencing between the EIS and any such study should be clear and reasonably limited such that both of the following considerations are duly satisfied:

1. Alerting the reader to the fact that the aspect in question is also being addressed in another parallel study; and
2. Enabling the reader to easily follow both the EIS and the other studies as stand-alone documents.

More detailed specifications are identified in the following pages.

1.0 DESCRIPTION OF THE PROPOSED DEVELOPMENT AND ITS CONTEXT

The description of the proposal is to include the aspects outlined below, and should take into account the entire proposal and any ancillary facilities and infrastructure connected with, or arising due to, the project.

1.1 Justification for the Proposal

1.1.1 Objectives

The purpose and objectives of the development and whether these are related to current legal obligations, policies or plans.

1.1.2 Demand

The current and expected requirement or demand for the proposed land uses, also explaining how the proposal will address the requirement/demand.

1.2 Description of the Physical Characteristics of the Whole Project and the Land Use Requirements during the Construction, Operational and Decommissioning Phases

The following aspects should be addressed for all phases of the project, clearly distinguishing between aspects relating to construction phase, the operational phase, decommissioning phase, or more than one phase. References to construction, operational phase and decommissioning phase also include ancillary site preparation, clearing, excavation, demolition/dismantling, and site reinstatement works, as relevant. Construction carried out in association with PA 04236/08 shall also be taken into consideration.

1.2.1 General characteristics

Description of the proposed development including size, area, height, volume, configuration/layout, general design, location and proposed elevations of buildings, hard and soft landscaping, access arrangements, boundary demarcation arrangements, land use requirements, and land take of ancillary facilities (including infrastructure, storage, servicing, security etc.). The description is to be consistent with the details submitted in the relevant permit applications, throughout both the EIA process and the development permission application process. Photographs and photomontages of the proposed development should also be included in this description.

1.2.2 Operational and production processes

The relevant operational and production processes and their main characteristics, including:

- The nature and quantity of materials used or generated;
- The source, type, quantity, composition and concentration of residues and emissions including water, air, soil pollution, noise, vibration, light, heat, radiation etc. resulting from the proposed project; and
- The expected annual and total emissions, including Greenhouse Gases (GHG), and the contribution to total national GHG emission on an annual basis.

1.2.3 Project management

An indicative framework outlining the key parameters and site management arrangements during construction, operation and decommissioning phases, including:

- Works methodology;
- Expected duration of all phases, as well as season, frequency and duration of interventions;
- Depths and volumes of excavation, and type of material to be excavated; and
- Types and quantities of raw materials and primary resources to be consumed, including water, energy, stone and other resources, and measures to reduce such consumption.

1.2.4 Access, transportation and related infrastructure

1. A forecast of the type, quantity and size of vehicles envisaged during each phase and their respective frequency of use, as well as an identification of the routes that vehicles will use to/from and within the site.

The required arrangements shall also be compared with the relevant existing situation (in terms of structural considerations, stability and state of roads, road width and gradient, turning circles and junctions, type of surfacing, and other physical or environmental constraints, etc). Interventions that would need to be carried out to accommodate the required vehicles (e.g. new or altered access roads), and sites/buildings/structures/features likely to be affected as a result, shall be identified accordingly.

2. Facilities for the storage, parking, on-site servicing, loading/unloading of equipment, vehicles and other machinery.

1.2.5 Water, sewerage, runoff management, energy, telecommunications, and ancillary infrastructure

1. Estimates of water management specifications of the development and the identification of the sources of water to be used, including the following:
 - The features and processes of the proposed development and its ancillary facilities which consume water, including estimates of water consumption and runoff/effluent generation during operation;
 - The sources of water (e.g. second-class water, public potable water mains, on-site production) envisaged to meet the projected demand;
 - The water-saving measures, if any, that are envisaged (e.g. use of low-flow fittings, reuse of harvested storm water runoff and rainwater, treatment and reuse of grey water/sewage), and details as to how such water will be used/managed; and
 - The facilities and structures to be installed in connection with the above (e.g. water production, purification, collection, storage, distribution and saving) including estimates of the sizing of pipelines, reservoirs and equipment.
2. Estimates of the energy-related specifications, including:
 - The features and processes of the proposed development and its ancillary facilities which consume energy, including estimates of consumption during operation. The analysis should consider, as relevant, the connected load (in MW or MVA), the overall power factor, the annual MWh split in terms of end-use (lighting, climate cooling/heating/ventilation, plant etc.) which reflects the expected use of the facilities;
 - The energy sources envisaged to meet the projected demand;
 - The facilities and structures to be installed in connection with the above (e.g. energy production, storage, distribution and saving) including estimates of the sizing of cables, buildings and equipment; and
 - The expected energy performance of the proposal, including building orientation, natural ventilation, construction materials, integration of low/zero-carbon technologies to meet energy needs; avoidance of features which increase energy consumption; and energy efficiency measures in the finishing and operation of the development.
3. Infrastructural services and utilities related to water and power supplies, sewerage, telecommunications and runoff management, and ancillary works (e.g. trenches, tunnels, culverts, switching/transformer stations, pumphouses, inspection chambers).
4. The extent to which the project can realistically be self-sufficient with regard to its energy and water needs, through appropriate measures such as the efficient use of energy and water, collection of rain and storm water for reuse, reuse of treated wastewater/sewage, technologies that reduce energy consumption, and the integration of alternative energy sources. Alternatives in terms of design, fabric and orientation of the buildings should also be explored and assessed.

1.2.6 Waste management

1. A sufficiently detailed indication of the waste management implications likely to arise from the project, including wastes generated by ancillary facilities and wastes which may arise from accidental spillages and leakages and from repair works. Wastes should be subdivided according to the relevant project phases.
2. The following information is to be provided for each waste stream, as relevant to each phase:
 - Identification of processes or activities that would result in waste generation;
 - European Waste Catalogue Codes for each waste stream, as per relevant legislation;
 - The projected quantities and rate of generation for each type of waste;
 - Information on waste handling and storage, on site as well as off site; and

- The method of transportation and frequency.

This information should be presented in table format as follows, and should also include cross-references to the relevant regulations, particularly The Waste Regulations (Legal Notice 184 of 2011, as amended):

PHASE:						
Phase	Type of waste	EWC Code	H-Code	Activity (e.g. sanding, scraping, power washing etc.)	Estimated quantities	Final permitted disposal location

3. The envisaged waste management arrangements using the Best Practicable Environmental Options (BPEO) available, and the envisaged efforts to minimise waste generation and to divert waste to reuse or recycling rather than disposal.
4. Layout plans (to scale) clearly showing all relevant waste management infrastructure and related facilities (e.g. bunded areas for storage of waste fuels, wheel-wash facilities, etc.), clearly distinguishing between temporary and permanent structures for each phase.

1.2.7 Longer-term developments

Additional future developments, land uses and other commitments that are ancillary or consequent to the project or are likely to arise in relation to the same project or its expansion, as well as longer-term needs of the proposal, including: ancillary infrastructure not accounted for in the previous sections; any consequent interventions/arrangements required to accommodate the development; any foreseeable extensions or updates to the proposal; any displacement of existing uses; and decommissioning.

2.0 ASSESSMENT OF ALTERNATIVES

An outline of the main alternatives studied and an indication of the main reasons for this choice, taking into account the relevant environmental effects and their prevention (or optimisation) at source. The following alternatives need to be duly considered, as relevant to the development itself (or to one or more phases thereof) and its requirements and constraints:

- 2.1 Alternative sites
- 2.2 Alternative technologies
- 2.3 Alternative layouts (including building heights, where relevant)
- 2.4 Downscaling of the project, or elimination of project components
- 2.5 Zero option (do-nothing scenario) — *i.e.* an assessment of the way the site would develop in the absence of the proposed project.

[Note: The zero option should be considered in sufficient detail as a plausible scenario throughout the EIS, wherever relevant, and not discarded upfront without proper discussion of its implications.]

- 2.6 Hybrids/combinations of the above

The findings of the assessment of alternatives should be summarised in a table format for ease of comparison.

3.0 A DESCRIPTION OF THE SITE AND ITS SURROUNDINGS (I.E. ENVIRONMENTAL BASELINE)

The existing environmental features, characteristics and conditions, in and around the proposed development site as well as in all locations likely to be affected by the development or by ancillary interventions and operations, are to be identified and described in sufficient detail, with particular attention to the aspects elaborated further in the next sections.

The consultants should also identify (and justify) wherever relevant:

1. The geographic area (e.g. watershed or other area of influence) that needs to be covered by each study;
2. The relevant sensitive receptors vis-à-vis the environmental parameter under consideration (e.g. residential communities, other users, natural ecosystems, specific populations of particular species, or individual physical features);
3. The location of the reference points or stations (e.g. viewpoints, monitoring stations, or sampling points) to be used in the study; and
4. Other methodological parameters of relevance, also noting that the assessment will normally require both desk-top studies and on-site investigations (including visual observations and sampling, as relevant).

Note: It is recommended that these details are discussed in advance with the Environment Protection Directorate prior to commencement of the relevant parts of the studies, in order to pre-empt (as much as possible) later-stage issues.

Wherever relevant to the environmental aspects under discussion, reference to legislation, policies, plans (including programmes and strategies) standards and targets, should also be made, such that the compatibility (or otherwise) of the proposal therewith is also factored into the assessment required by **Section 4** below. The discussion should cover the following aspects, in the appropriate level of detail:

- Supra-national (e.g. European Union; United Nations; or other international or regional) legislation, directives, policies, conventions, protocols, treaties, charters, plans and obligations;
- National legislation, policies and plans (e.g. Structure Plan; National Environment Policy); and
- Sub-national legislation, policies and plans (e.g. local plans, site-specific regulations, action plans, management plans, and protective designations such as scheduling or Natura 2000).

Note: In addition to already in-force legislation, policies and plans, the discussion should also cover any foreseeable future updates (or new legislation, policies and plans) likely to be fulfilled, affected or compromised by the proposed project. Furthermore, it should be noted that some cross-cutting legal/policy instruments (e.g. Water Framework Directive) may need to be factored into more than one aspect of the discussion.

3.1 Land cover and Land/Sea Uses

A description of the land cover and land uses within the area of influence of the project, including roads, footpaths and public access routes. Details including nature, magnitude, proximity to site, etc. should be included.

3.2 Water bodies (including Terrestrial, Underground)

The study should identify the hydrological, hydromorphological and physicochemical characteristics of the water bodies and water resources in the area under investigation, including:

1. The hydrology of the site and its surroundings (incl. Wied il-Buni and Wied il-Klima), including all relevant features and dynamics, such as: aquifers; springs; surface waters; wetlands; watercourses; valley catchments; etc, also cross-referring to hydrogeological factors as relevant;
2. The type, size and physical characteristics of any aquifers and surface water bodies within the area of influence of the site, including: the nature of the water body (e.g. aquifer, flowing surface water, etc.); whether the water body is ephemeral or permanent; depth; type of bottom etc.;
3. Natural and anthropogenic dynamics including groundwater recharge patterns; pumping and abstraction patterns; on-site and off-site drainage patterns; run-off patterns; and flood risks; and
4. Water quality (salinity, pollutant load, sediment load and characteristics, microbiological load, BOD & COD, transparency, temperature, etc.), with particular reference to any established quality parameters (e.g. effluent discharge parameters; objectives and requirements of the Water Framework Directive and related instruments).

3.3 Ecology

The assessment should include:

1. An investigation of the ecology of the site surroundings (including, as relevant: flora, fauna, and burrowing organisms, and their habitats and ecosystems), duly covering the relevant seasons (e.g. wet and dry seasons) to ensure adequate coverage of all relevant species and ecosystem components. This study must also include the surrounding valleys, i.e. Wied il-Buni and Wied il-Klima;
2. A reporting of the conservation status and ecological condition of the area and the state of health of its habitats, species and ecological features;
3. A reporting of all protected, endangered, rare, unique, endemic, high-quality, keystone, invasive/deleterious, or otherwise important species, habitats, ecological assemblages, and ecological conditions found in the area under study; and
4. A prediction of the potential impacts of the proposed project on the ecology of the site and its surroundings, including loss, damage or alteration of habitats and species populations.

In particular, the study should identify all relevant species and assemblages (e.g. protected species or habitats, key species relevant to habitat characterisation, and monitoring indicators), and assess their abundance and distribution patterns as well as the species' ecological niches. The findings should be supported by adequate maps and photographs. Classification of habitat types and species should be conducted in accordance with recognised classification systems (e.g. EUNIS and Palaeartic), to MEPA satisfaction.

Note 1: *Should the proposal fall within (or be likely to have significant impact on) a Natura 2000 Site, Special Area of Conservation (SAC) or Special Protection Area (SPA), a stand-alone Appropriate Assessment in terms of the Flora, Fauna and Natural Habitats Protection Regulations may be required. In such instances, separate Terms of Reference are issued for the Appropriate Assessment.*

Note 2: *Where the area of influence encompasses both marine and terrestrial environments, one or more of the sections indicated in these specimen TORs may need to be restructured accordingly to reflect the specific circumstances (e.g. separate reports for marine and terrestrial ecology).*

3.4 Architectural, Archaeological, Historical & Cultural Heritage and related Material Assets

The study should identify all relevant cultural heritage assets, including archaeological, historical, and architectural heritage, elements of vernacular or rural architecture (e.g. rubble walls, huts, wells, irrigation channels, farmhouses, etc.), and the holistic cultural landscape. It should:

1. Identify and document all relevant information about cultural heritage assets within the area of study (120 metres and 500 metre radius around the footprint);
2. Describe and analyse the cultural landscape;
3. Assess the cultural heritage significance of each feature and of the area of study;
4. Predict and assess the impacts and risks posed by the proposed project during all phases, including impact on the heritage assets and archaeological remains (whether on the surface or buried) and their context, as well as visual or other impact on the cultural landscape; and
5. Propose statutory and physical protection of the individual features and of the site.

Note: *For the purposes of this document, cultural heritage is defined by Article 2 of the Cultural Heritage Act (2002). This includes movable or immovable objects of artistic, architectural, historical, archaeological, ethnographic, palaeontological and geological importance.*

3.4.1 Detailed specifications for the study

The assessment should provide exhaustive and coherent information about the cultural assets present, their relation to past/historic events, the cultural relevance of the site and its environs throughout history, the archaeological potential within the area of study, and the current state of play vis-à-vis the survival, location, and vulnerability of the identified features. This study should include, as relevant:

1. An on-site surface visual survey within the area of study;
2. An analysis of existing literature (including old manuscripts, reports of previous discoveries, as well as cartographic, photographic, and other graphic material), together with a bibliography of sources consulted and (where reasonably possible) a reproduction of salient excerpts or figures;
3. Desktop and archival research to the 500 metre radius;
4. Fieldwork and research, including "field walking", topographic survey and remote sensing as may be necessary to the 120 metre radius;
5. An analysis of toponyms;

6. An identification and recording of all features (including pottery scatters), also indicating their precise location and condition. The study should attempt to determine the typologies of cultural features (including military or civil architecture from the Knights period to British period, vernacular structures, distinguished buildings or gardens and field systems and agricultural features such as irrigation systems and rubble walls) on the basis of form, materials, technology, intended use, dating/phasing, architectural details and other distinctive characteristics; and
7. Precise recording of the features on a map (scale 1:2500 or better).

Note: Field investigations are subject to legal restrictions. Unless explicitly directed otherwise by the Superintendence of Cultural Heritage, collection of pottery shards or other artefacts is not allowed, and on-site physical archaeological interventions (e.g. excavations, site disturbance) need prior authorisation.

3.4.2 Recording Specifications

Raw information for each observed feature should be presented in data cards conforming to the specimen attached in *Appendix 2*. Each feature should be individually identified with a consecutive reference number. The reference number should be used throughout the report when cross-referencing between maps, photographs, data cards and text. The information on each card should include the following information:

1. A short description of the feature, and (where available) its name;
2. Co-ordinates recorded up to 5 digits for each northings and eastings based in the local/UTM grid reference;
3. The site location and address;
4. The site clearly indicated on an up-to-date map (1:2500 scale or better);
5. Representative good-quality photographs taken from various angles (the location, direction and angle of the photograph should also be indicated on a map base);
6. A good-quality scaled diagram/sketch, also indicating the north point and relating the feature to its immediately surrounding structures;
7. An indication of the significance of each feature, with a proposed grading following the relevant MEPA-recognised criteria (e.g. the grades established in terms of Structure Plan UCO and ARC policies);
8. An indication of the existing and/or currently proposed legislative and physical protection, or (in their absence) a recommendation in this regard;
9. Details of the current and proposed use, and any suggested enhancement;
10. A cultural heritage Risk Assessment Map examining the various impacts of the proposed project;
11. Bibliographical references as relevant; and
12. Name of surveyors and date of compilation.

3.5 Air Quality and Odour

This study should clearly establish the current background levels of pollution (including dust) and odour, and should include a clear comparison to the relevant reference and limit values as specified in the relevant legislation as well as in any other relevant guidance documents. Details on prevailing wind and climate conditions should also be included, amongst other relevant parameters.

The methodology to be used should be submitted for the Environment Protection Directorate's evaluation prior to commencement of the studies. Unless otherwise agreed, studies of the background levels are to be conducted over a period of at least 6 weeks and should be as follows:

1. **NO_x**: Should the proposed development be sited in an area with heavy traffic, real-time measurement of hourly concentrations of NO_x, particularly during rush hours is required. Diffusion tube monitoring should take place over two 3-week periods, with two 3-week averages and one 6-week average that would be compared to the annual limit value;
2. **PM₁₀**: Daily measurements of PM₁₀ concentrations are to be compared with the daily limit values. Furthermore, two 3-week averages and one 6-week average are to be compared with the annual limit value;
3. **PM_{2.5}**: Two 3-week averages and one 6-week average are to be compared with the annual limit value; and
4. **Other**: Other pollutant parameters may be relevant vis-à-vis specific development types, for example those involving industrial emissions.

The sampling points for the air-quality and odour study, one of which should be at the most sensitive receptor in the prevailing wind direction, should also be submitted to EPD prior to the commencement of studies.

The study should provide a sufficiently detailed baseline to enable:

- An adequate determination of how the current air quality and odour levels (including the locality of Birzebbuġa and Bengħisa area) will be affected by the project (including its emissions to air during all relevant phases);
- A detailed breakdown, as relevant, by source, type, quantity, composition, concentration and distribution of each pollutant (both non-hazardous and hazardous);
- Emissions of hazardous air pollutants and odours during the operation stage and their effects on on-site workers, sensitive receptors in the surrounding area, the general public and on the environment; and,
- An adequate estimation of indirect impacts on air quality due to increased vehicular traffic (especially on the locality of Birzebbuġa), using a suitable traffic model.

3.6 Noise, Vibrations and Exterior Lighting

This study should provide sufficiently detailed information on representative background levels of noise, vibration and nocturnal lighting (as relevant), as a baseline for assessing the levels and effects expected to result from the development, including any short- and long-term changes, peaks and fluctuations as well as their acute or chronic impacts. The study should also take into account other relevant factors such as:

- Cumulation with other existing sources including traffic, and with other predicted sources such as new developments;
- Additional effects of road traffic associated with operations on the site;
- Sensitive receptors (e.g. residents, schools, hospitals, recreational areas, fauna and avifauna, natural ecosystems); and
- The potential for attenuation or exacerbation by 'environmental' factors (e.g. topography, vegetation, physical barriers etc.), and for mitigation (e.g. shielding, muffling/soundproofing, reduced lighting, etc.).

Note: In the case of light pollution, the study needs to consider, among others, glare (e.g. the blinding light which is a danger to motorists/pedestrians and to fauna), light trespass (light straying into an area where it is not desired or required) and sky glow ('wasted' light directed upwards), together with any other relevant variables which are relevant to the determination of impact on the surrounding receptors.

The study results should include measurable parameters (e.g. frequency, intensity) as relevant, and should be evaluated against appropriate reference values². The reference points and measurement locations used should be approved by MEPA prior to commencement of studies and, unless otherwise indicated, should be at ground level.

3.7 Infrastructure and Utilities

The assessment should investigate the currently available infrastructural services (including water supply, energy supply, sewerage, telecommunications infrastructure, access roads, parking, etc.), including details about their carrying capacity, physical condition and other relevant practical considerations. It should also compare this information to the infrastructural demands of the project as identified in **Section 1** above, so as to clearly indicate:

1. Whether the current utilities are adequate to meet the demand arising from the proposed development;
2. Whether any significant loading, congestion or damaging of the infrastructural or transport network (especially on the locality of Birzebbuġa) is envisaged; and
3. Whether any new or upgraded services/arrangements will be rendered necessary, both in the short-term and in the longer-term. If any requirement for new infrastructure (or upgrading, alteration or extension of the existing infrastructure) is envisaged, the relevant details including associated works and their environmental implications should also be indicated.

The assessment should also identify any existing or projected infrastructural services located within the area of influence of the development (even if not related to the demands of the development) that might be affected by the development or which may need to be displaced or diverted as a consequence of the development or its ancillary operations and interventions.

² Unless otherwise specifically indicated, it is recommended that: ISO 1996 and ISO 9613 (all series) standards are used for the noise assessment; BS6472 (relating to human exposure to vibration) and BS7385 (covering the effects on buildings) are used when studying vibration; BS 5228 is used for the assessment of construction noise; and BS 4142 is used vis-à-vis noise complaints.

3.8 Public Access

The assessment should identify the current public access arrangements, including existing footpaths and other public access routes, and should clearly indicate whether these would be affected and how. The study must also include any potential impacts on the locality of Birżebbuġa.

Wherever any new or altered arrangements are proposed, these should be clearly identified and their environmental implications should also be indicated.

3.9 Other relevant environmental aspects and features

Other relevant environmental features or considerations not identified in the preceding sections should also be identified and described, as relevant.

4.0 ASSESSMENT OF ENVIRONMENTAL IMPACTS AND ENVIRONMENTAL RISKS

All likely significant effects and risks posed by the proposed project on the environment during all relevant phases (including construction/excavation/demolition, operation and decommissioning) should be assessed in detail, taking into account the information emerging from Sections 1, 2 and 3 above. Apart from considering the project on its own merits (*i.e.* if taken in isolation), the assessment should also take into account the wider surrounding context and should consider the limitations and effects that the surrounding environmental constraints, features and dynamics may exert on the proposed development, thereby identifying any incompatibilities, conflicts, interferences or other relevant implications that may arise if the project is implemented.

In this regard, the assessment should address the following aspects, as applicable for any category of effects or for the overall evaluation of environmental impact, addressing the worst-case scenario wherever relevant:

1. An exhaustive identification and description of the envisaged impacts;
2. The magnitude, severity and significance of the impacts;
3. The geographical extent/range and physical distribution of the impacts, in relation to: site coverage; the features located in the site surroundings; whether the impacts are short-, medium- or long-range; and any transboundary impacts (*i.e.* impacts affecting other countries);
4. The timing and duration of the impacts (whether the impact is temporary or permanent; short-, medium- or long-term; and reasonable quantification of timeframes);
5. Whether the impacts are reversible or irreversible (including the degree of reversibility in practice and a clear identification of any conditions, assumptions and pre-requisites for reversibility);
6. A comprehensive coverage of direct, indirect, secondary and cumulative impacts, including:
 - interactions (*e.g.* summative, synergistic, antagonistic, and vicious-cycle effects) between impacts;
 - interactions or interference with natural or anthropogenic processes and dynamics;
 - cumulation of the project and its effects with other past, present or reasonably foreseeable developments, activities and land uses and with other relevant baseline situations; and
 - wider impacts and environmental implications arising from consequent demands, implications and commitments associated with the project (including: displacement of existing uses; new or increased development pressures in the surroundings of the project; and impacts of any additional interventions likely to be triggered or necessitated by situations created, induced or exacerbated by the project);
7. Whether the impacts are adverse, neutral or beneficial;
8. The sensitivity and resilience of resources, environmental features and receptors vis-à-vis the impacts;
9. Implications and conflicts vis-à-vis environmentally-relevant plans, policies and regulations;
10. The probability of the impacts occurring; and
11. The techniques, methods, calculations and assumptions used in the analyses and predictions, and the confidence level/limits and uncertainties vis-à-vis impact prediction.

The impacts that need to be addressed are detailed further in the sub-sections below.

4.1 Effects on the environmental aspects identified in Section 3

The assessment should thoroughly identify and evaluate the impacts and implications of the project on all the relevant environmental aspects identified in Section 3 above, also taking into account the various considerations outlined in the respective sections.

4.2 Impacts related to Climate Change and Climate Change Adaptation

The assessment should address the following aspects, as relevant:

1. The contribution of the project to greenhouse gas (GHG) emissions and climate change, including:
 - (i) The direct, indirect and off-site GHG emissions and related impacts during all relevant phases of the project, including those arising as a result of the electrical power demand of the project;
 - (ii) Any massive GHG emissions that may occur as a consequence of accidents or malfunctions;
 - (iii) The impacts of the proposal on carbon sinks (e.g. wooded/afforested areas, agricultural soils, landfills, wetlands, and marine environments);
 - (iv) The components of the project that are expected to contribute to renewable energy generation on site, including a quantification and critique of their reliability and actual net contribution to climate change mitigation as well as an identification of the impacts of such components on other aspects of the environment (e.g. landscape, land take, avifauna); and
 - (v) The implications of the project and its operations and ancillary demands on National GHG emission targets.
2. The implications of climate change on the proposal, including:
 - (i) The aspects/elements of the project that are likely to be affected by changes or variability in climate-related parameters (e.g. temperature, humidity, weather patterns, sea level, etc.);
 - (ii) The potential impacts that such changes may have on the proposal, including any possible impacts resulting from changes to multiple parameters; and
 - (iii) The adaptability of the project and its components and operations vis-à-vis the relevant climate change parameters and trends.

4.3 Environmental risk

The assessment should also address, in sufficient detail, any relevant environmental risk (including major-accident scenarios such as contamination, emissions, explosions, blast, flooding, major spillages, etc.) likely to result in environmental damage or deterioration. The range of accident scenarios considered should exhaustively cover, as relevant:

1. one-time risks (e.g. during construction or decommissioning works);
2. recurrent risks during project operation; and
3. risks associated with extreme events (e.g. effect of earthquakes or natural disasters on the project).

The assessment should include, as relevant: a quantification of the risk magnitude and probability; and risk analysis vis-à-vis any hazardous materials stored, handled, or generated on site or transported to/from the site.

4.4 Effects on Human Populations resulting from impacts on the environment

This assessment should also identify any impacts of the development on the surrounding and visiting population (e.g. effects on public health or on socio-economic considerations), that may result from impacts on the environment. In the case of health-related effects, reference should be made to published epidemiological and other studies, as relevant, and the views of the Environmental Health Directorate should be sought.

4.5 Other Environmental Effects

Any other environmental effects deemed relevant to the project but not fitting within any of the above sections should also be identified and assessed.

5.0 REQUIRED MEASURES, IDENTIFICATION OF RESIDUAL IMPACTS, AND MONITORING PROGRAMME

5.1 Mitigation Measures

A clear identification and explanation of the measures envisaged to prevent, eliminate, reduce or offset (as relevant) the identified significant adverse effects of the project during all relevant phases including construction, operation and decommissioning [see **Section 1.2.3** above].

As a general rule, mitigation measures for construction-phase impacts should be packaged as a holistic Construction Management Plan (CMP). Whilst the detailed workings of the CMP may need to be devised at a later stage (e.g. after the final design of the project has been approved and/or after a contractor has been appointed), the key parameters that the CMP must adhere to for proper mitigation need to be identified in the EIS. Broadly similar considerations also apply vis-à-vis operational-phase impacts [which may need to be mitigated through an operational permit] and decommissioning-phase impacts [see **Section 5.4** below], where relevant.

Mitigation measures for accident/risk scenarios should be packaged as a holistic plan that includes the integration of failsafe systems into the project design as well as well-defined contingency measures.

The recommended measures should be feasible, realistically implementable to the required standards and in a timely manner, effective and reliable, and reasonably exhaustive. They should not be dependent on factors that are beyond the developer's and MEPA's control or which would be difficult to monitor, implement or enforce. The actual scope for, and feasibility of, effective prevention or mitigation should also be clearly indicated, also identifying all potentially important pre-requisites, conditionalities and side-effects.

5.2 Residual Impacts

Any residual impacts [*i.e.* impacts that cannot be effectively mitigated, or can only be partly mitigated, or which are expected to remain or recur again following exhaustive implementation of mitigation measures] should also be clearly identified.

5.3 Additional Measures

Compensatory measures (*i.e.* measures intended to offset, in whole or in part, the residual impacts) should also be identified, as reasonably relevant. Such measures should be not considered as an acceptable substitute to impact avoidance or mitigation.

If the assessment also identifies beneficial impacts on the environment, measures to maximise the environmental benefit should also be identified.

In both instances, the same practical considerations as indicated vis-à-vis mitigation measures should also apply.

5.4 Decommissioning Plan

A decommissioning plan (DP) should also be proposed to address the following circumstances, as relevant:

1. Removal of any temporary or defined-lifetime development (or of any structures, infrastructure or land use required temporarily in connection with it) upon the expiry of their permitted duration; and
2. Removal of the development (or of any secondary developments, infrastructure or land use ancillary to it) in the event of redundancy, cessation of operations, serious default from critical mitigation measures, or other overriding situations that may emerge in future.

The DP should also include, as relevant, a phasing-out plan, proposals for site remediation or decontamination, and methodological guidance on site reinstatement or appropriate after-use.

5.5 Monitoring Programme

A realistic and enforceable programme for effective monitoring of those works envisaged to have an adverse or uncertain impact. The monitoring programme should include:

1. Details regarding type and frequency of monitoring and reporting, including spot checks;
2. The parameters that will be monitored, and the monitoring indicators to be used;
3. An effective indication of the required action to address any exceedances, risks, mitigation failures or non-compliances for each monitoring parameter;
4. An evaluation of forecasts, predictions and measures identified in the EIS; and
5. An indication of the nature and extent of any additional investigations (including EIAs or ad hoc detailed investigations, if relevant) that may be required in the event of any contingencies, unanticipated impacts, or impacts of larger magnitude or extent than predicted.

The programme should address all relevant stages, as follows:

- (a) Where relevant, monitoring of preliminary on-site investigations that may entail significant disturbance or damage to site features (e.g. archaeological excavations, geological sampling, or any works that require prior site clearance or any significant destructive sampling);
[Note: Official written consent from the competent authorities (e.g. Superintendence of Cultural Heritage) may also be required for such interventions.]
- (b) Monitoring of the operational phase, except where otherwise directed by MEPA (e.g. where monitoring would be more appropriately integrated into an operating permit); and,
- (c) Where relevant, monitoring of the decommissioning phase, including the situation before initiation of works, during appropriate stages of progress, and after completion of works.

5.6 Identification of required authorisations

The assessment should also identify all environmentally-relevant permits, licences, clearances and authorisations (other than the development permit to which this EIS is ancillary) which must be obtained by the applicant in order to effectively implement the project if development permission is granted. Any uncertainty, as to whether any of these pre-requisites is applicable to the project, should be clearly stated.

Note on Sections 5.1 to 5.6 above:

The expected effects, the proposed measures, the residual impacts, the proposed monitoring etc. should also be summarised in a user-friendly itemised table that enables the reader to easily relate the various aspects to each other. An indicative specimen table is attached in **Appendix 3**.

Regulation 28: Identification of consultants and contributors

Extract:

- 28. (1) *The environmental impact statement shall list the registration number and the names of the consultants and contributors responsible for the preparation of the environmental impact statement, environmental survey reports, appendices, non-technical summary and other components of the statement.*
- (2) *The consultants who are responsible for a particular analysis, including analysis in the environmental survey reports, shall be identified.*
- (3) *All consultants and contributors employed in the environmental impact assessment shall sign a declaration stating that the particular study (or part thereof) was solely carried out by them and that they take responsibility for any statement and conclusion contained therein. This signed declaration shall be included with each environmental survey report included with the environmental impact statement.*

Signed declaration in accordance with sub-regulation 28(3):

This declaration is to be submitted with each environmental survey report forming part of the EIA.

Attn: Director of Environment Protection (MEPA).

I _____, who carried out the study (or part thereof) on _____ for the EIA for the proposed _____, hereby declare that such study was solely carried out by me and take responsibility for any statement and conclusion contained therein.

Date

Signature

Regulation 29: Conflict of interest

Extract:

- 29. (1) *In the interest of fairness, objectivity and the avoidance of bias, all consultants shall required to sign and abide by a declaration that they have no personal or financial interest in the proposed development.*
- (2) *The Director of Environment Protection shall not approve consultants, groups of consultants or consultancy firms that are in any way associated with any company, association or grouping that has any direct or indirect personal, association or grouping that has any direct or indirect personal, professional or financial interest in the proposed development.*
- (3) *The Director of Environment Protection shall not approve any environmental impact statement or environmental planning statement produced by a consultant or group of consultants, one or more of whom does not comply with the provisions of sub-regulations (1) or (2) of this regulation.*

Signed declaration in accordance with Sub-regulation 29(1):

This declaration is to be submitted when proposing the list of EIA Consultants for approval.

Attn: Director of Environment Protection (MEPA)

I _____, herby declare that I have no personal or financial interest in the proposed development, namely _____. Moreover, I declare that I am not in any way associated with any individual, company, association or grouping that has any direct or indirect, personal, professional or financial interest in the abovementioned proposed development.

Date

Signature

APPENDIX 2: SPECIMEN DATA CARD FOR ARCHAEOLOGY/CULTURAL HERITAGE ASSESSMENT

MEPA PROTECTIVE INVENTORY OF THE MALTESE CULTURAL HERITAGE HERITAGE DATA CAPTURE SHEET						Ref. No.	
Location		Category	Type	Site Location (Address)			
Eastings		Northings	Feature	Period - Year			
S.S. No. 1	S.S. No. 2	Description					
S.S. No. 3	S.S. No. 4						
Date							
Negative No.	Film No.						
Present Utilization							
Existing Legal Protection			GN. Number			GN. Date	
Comments							
Buffer Zone	A	B	C	D	E	Others	
Eastings							
Northings							
Site Map							
Scale 1 : 2500							

Archaeological Characteristics – Sketch/Scaled drawings:	
Condition:	Degree of Protection (Structure Plan policies UCO7 or ARC 2):
State of Security:	Proposed Utilization:
Basic Bibliography:	
Compiled by:	Revised by:
Checked by:	Checked by:
Date:	Date:

APPENDIX 3: SPECIMEN IMPACT TABLE

Impact type and source			Impact receptor		Effect & scale							Probability of impact occurring (Inevitable, Likely, Unlikely, Remote, Uncertain)	Overall impact significance	Proposed mitigation measures	Residual impact significance	Other requirements (monitoring, authorisations, etc)
Impact type	Specific intervention leading to impact	Project phase (construction/ operation/ decommissioning)	Receptor type	Sensitivity & resilience toward impact	Direct/ Indirect/ Cumulative	Beneficial/ Adverse	Severity	Physical / geographic extent of impact	Short-/medium- / long-term	Temporary (indicate duration)/ Permanent	Reversible (indicate ease of reversibility) / Irreversible					

[Insert definition of relevant criteria used to describe the impacts]